THE EFFECT OF DEVELOPMENTAL ACTIVITIES, EMBEDDED INTO PARENT'S ACTIVITIES OF DAILY LIVING, ON SUPINE SLEEPING INFANT MILESTONE DEVELOPMENT

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DECLARATION

I declare that this dissertation is my own work. It is being submitted for the degree of Masters of Science in Occupational Therapy at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University.

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ABSTRACT

Therapeutic intervention should take humans' daily routines into account or it is unlikely to be assimilated into everyday practice. This is particularly true for the mothers of young children. The purpose of this study was to examine the effect of a prone postural control programme, by inserting infant stimulation activities in to the activities of daily living of mothers.

30 mother-infant dyads were randomly assigned at eight weeks postpartum, to an intervention or usual care group. Following a four month period in which the intervention group followed a prone activity programme developed by the researcher, the infants were reassessed. The Peabody Developmental Motor Scales (2nd Ed) were used to evaluate the programme's efficacy and the results demonstrate a significant difference ($p \leq 0.00$) in the total motor development between the two groups post intervention. Thus a 'prone playing' programme given to mitigate developmental delay associated with supine sleeping, was successful when embedded into the mother's daily routine.

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF APPENDICES

DEFINITIONS OF TERMS:

- **Activities of Daily Living** – "are tasks of self-maintenance, mobility, communication, home management and community living that enable an individual to achieve personal independence."[1 p 463] For the purpose of this study, the activities of daily living pertaining to mothering include, but are not restricted to, baby care, home management and those work, leisure, social and personal management tasks which may have been applicable prior to the infant's birth.

- **Occupationally-embedded exercise** – are exercises that are inserted/incorporated in everyday tasks that are occupationally appropriate for the individual and provide meaning and motivation other than the achievement of exercise,[2] such that the "exercise occurs as a byproduct of pursuing task-specific goals."[3 p 27]

- **Sleep position -** The position in which parents place their infants to sleep during the day and night.[4] This may include prone, supine or side-lying positions, or a combination thereof.[5]

- **Sudden Infant Death Syndrome –** "The sudden death of an infant under one year of age, which remains unexplained after a thorough case investigation, including performance of a complete autopsy, examination of the death scene and review of the clinical history."[6 p 681]

- **Programme development** - "Creating and evaluating an approach to service delivery for a defined client group."[7 p 491]

- **Mechanism of change -** "Theoretically and empirically accounting for how a particular change occurs as a consequence of participating in an intervention."[7 p 493]

- **Tummy time –** is a conversational term, used to explain to parents the prone positioning of an infant when they are awake, but supervised, to encourage development of muscles of the head and neck and shoulders.[8, 9]

ABBREVIATIONS:

AAP: American Academy of Pediatrics

ADL: Activities of Daily Living

AIMS: Alberta Infant Motor Scale

AP: Activity Profiles

BTS: "Back to Sleep"

FMQ: Fine Motor Quotient

GMQ: Gross Motor Quotient

IPCP: Infant Postural Control Programme

PDMS-2: Peabody Developmental Motor Scales – 2nd Editions

SIDS: Sudden Infant Death Syndrome

TMQ: Total Motor Quotient

CHAPTER 1 INTRODUCTION

1.1 Background to the Study

"Dismantling or revising of daily routines for the insertion of intervention requires a deep understanding of family routines and their meaning to family members." (p251)[10]

Human occupational engagement, or how humans construct their routines and enfold themselves in the activities of their lives, is a core concept of occupational therapy.

None are as involved in this orchestration of time as those undertaking the work of 'mothering'. Mothers are afforded the role of being the keepers of time,[10] and are charged with the task of managing both their own time and that of their children through the construction of efficient routines.

The case in point to the introductory quote, exploring the insertion of apparently benign interventions, is the parental education campaign designed to reduce the incidence of Sudden Infant Death Syndrome (SIDS). The "Back to sleep" (BTS) campaign and its corollary, "prone to play", is designed to mitigate the effects of developmental delay found to be caused by infants sleeping in supine.

The programme was advocated in the early 1990's, at the prompting of a variety of paediatric research forums such as (but not limited to) the American Academy of Pediatrics (AAP), who established a link between the prone sleeping posture and SIDS.[4] Although it is

recognized that the prone posture is not the only risk factor for SIDS[11, 12] it is considered to be a significant one.[12] The BTS campaign aims to reduce prone sleeping to less than 10% of the American infant population.[11] A shift in family education took place that encouraged parents to put their newborn infants to sleep lying on their sides or back, rather than prone.[5] Various results suggested an initial reduction in the SIDS rates of up to 50%, following the implementation of this education programme, in countries around the world.[13] In the United States, the AAP recommendations also resulted in a change in policy in crèches and day care settings, resulting in 37.3% of facilities exclusively placing the infants in their charge to sleep on their backs.[14]

Within a relatively short period of time of the BTS programme being initiated, doctors noticed, and anecdotally described, a delay in developmental milestones in babies who were placed supine to sleep.[5] This has subsequently been researched and several studies support these observations.[15-18]

A significant difference in rolling at four months between infants who slept prone compared to those who slept either supine or in side-lying was found by Jantz, Blosser and Fruechting (1997).[5] No specific data were collected regarding how the babies were placed during the day time, and it is assumed that this is the same position as the sleeping position, based on the work of Mildred, Beard, Dallwitz and Unwin.[19] Many of these early findings have been duplicated. Babies that slept in supine were slower in supported sitting, in creeping on their stomachs, four-foot crawling and pulling to stand.[20]

Further, the BTS education programme expounded the benefits of using a "prone position to play"[11, 14] for infants, in order to mitigate the negative effects of sleeping in supine. It has been found that in homes and day care facilities alike there is a reduced implementation

of the "prone to play" principle and studies have suggested that many people simply are not aware of this second part of the campaign.[14] Some parents or caregivers are fearful of putting their infants prone at any time[19] and still others realize, after a period of time, that the infant dislikes the prone position, and consequently parents reduce the use of a prone position in their routine.[16] It is also suggested that parents find it difficult to gauge how much time their baby spends in prone and that the measured time is actually a fraction of that which parents estimated it to be.[5, 14, 16]

If one considers the "prone to play" component of this campaign from a mother's point of view the juxtaposition of *time* and *resources* which are assumed in the idea of a 'simple intervention' comes into play. The apparent simplicity in the tasks of caring for an infant masks the complexity of the balancing of time. Therapists, therefore, have to consider very carefully what it means to add a 'simple stimulation activity' for infants to a mother's routine. Although keenly aware of the need to provide developmental opportunities for their children, mothers experience a sense of time pressure, such that, for every task added, another task has to give way.[10, 21]

Further, the literature relating to a family-centred therapy approach suggests that intervention strategies need to be tailored to real life for the *parents* in order to be incorporated into practice. Rather than impacting directly on infants, early intervention practices should aim to extend the parents range of skills that they can employ to help their child on an ongoing basis.[22] Studies indicate that mothers find it difficult to implement traditional, therapist-directed interventions at home,[23, 24] but that they are skilful at adjusting and adapting what they are shown in therapy in order to help their children.[24] The focus of the intervention needs to be the building of the parent-child relationship, in order to optimize the developmental potential of an infant.[25]

The problem for parents in implementing the 'prone to play' principle is therefore, that it stands outside of the tasks of human occupation that a mother-infant dyad would normally be engaged in, or taxes the energy, time and resources of that dyad. In order for a programme to successfully be translated into habit it needs to be integrated into the normal occupational tasks that a new mother has to master.[7]

1.2 Statement of the Problem

Now that a substantial move toward the BTS campaign is in place, research has shown a delay in milestone achievement in babies who sleep supine as opposed to prone.[16] The panacea for this – as nurses and midwives at Well Baby clinics advise parents – is for parents to put their babies in prone during awake and supervised time, but this is often difficult to achieve, because this advice falls outside of the normal activities that mothers build into their daily routines.[26] Further, many parents do not use prone positioning with their infants for fear of the perceived risks. The advice given by the AAP to 'play in prone' is seldom conveyed with the same degree of importance as is 'sleeping in supine'. In failing to understand that this directive, outside of the normal activities of daily living (ADL), is too onerous, nurses, doctors and therapists involved in early infant development leave mothers to attempt to fit supervised prone time in the time spaces between feeding, bathing, dressing, caring for and interacting with their infants. Despite a keen awareness of the developmental needs of their infants, this extra time is more than most mothers can incorporate in their daily routine.

1.3 Purpose of the Study

The purpose of this study is to determine whether a programme of defined activities, embedded into a mother's ADL, will affect the

motor development of supine sleeping infants up to six months of age. Infants included in the programme, which challenges their postural muscles, will be compared to a usual care group of supine sleeping infants who are not involved in this programme.

1.4 Justification for the Study

The extent to which some infants are delayed may be sufficient to result in a misdiagnosis of developmental delay or to prompt therapeutic intervention,[16, 27] which may be unnecessary. It also appears that it is difficult for parents to gauge how much time their infants are actually spending playing in prone. This suggests that the current practice, of providing parents with a 'target' of a certain length of time spent in prone per day, would be ineffective advice for doctors, nurses and therapists to use.

Further, since parents gauge the well-being of their infants in the first year of life by their developmental milestones, it is anxiety provoking for them to realise that their infant is delayed and any means to reduce that anxiety is a worthy pursuit for the medical profession.

Lack of prone positioning may result in the excessive use of baby seats, baby bouncers and walking rings.[28] Mothers make use of infant positioning tools as an expedient means to entertain or protect their infants while they are involved in normal tasks of ADL.[28] If one could embed the tasks, for infant stimulation, into tasks which a mother otherwise needs to do, would she be able to enfold both tasks into her construction of a routine?

Occupational therapists work to understand how humans construct routines and habits. Without that understanding, there is a sense that to simply add an exercise or intervention to a client's life is a

small matter, easily accomplished by the client, when the reality might be completely opposite.

This research addresses a method of teaching parents to challenge the postural muscles of their infants through the vehicle of an ADL-embedded postural control programme, in a manner that is more likely to become habitual in the parents normal routine. This may also reduce the observed delays for these infants who are placed supine to sleep.

1.5 Aims of the Study

- To design a postural control programme for infants, in which defined stimulatory activities are embedded into the everyday activities of the parents, in keeping with the occupational therapy philosophy of embedded activity.
- To determine whether parents are able to incorporate new techniques into their daily activities, which challenge the postural control of their infants, and
- To evaluate whether this is developmentally advantageous to supine sleeping infants.

1.6 Objectives of the Study

- To design and pilot a postural control programme for infants, in which defined prone activities are embedded into the everyday activities of the parents.
- To compare the motor development of supine sleeping infants after six months of age whose parents incorporate an activities programme, embedded into their normal activities of daily

living (ADL), that challenge the infants' postural muscles with infants whose parents do not.

- To evaluate the participation of parents in incorporating postural control activities which are embedded into their own ADL.

1.7 Null Hypothesis

There will be no difference after six months, in the motor development of supine sleeping infants, whose parents incorporated activities embedded into their normal ADL to challenge their infants' postural muscles and those infants whose parents did not.

CHAPTER 2 LITERATURE REVIEW

In this chapter relevant literature is reviewed to provide an overall view of parent-child interactions and the role that stimulation programmes play in that dynamic. The chapter is divided into four sections:

- Mothering and the challenges and successes involved in enfolding a stimulation programme into a normal daily routine.
- The "Back to sleep" campaign and Sudden Infant Death Syndrome (SIDS), its risks and risk reduction.
- A brief discussion on the theoretical background of occupationally-embedded activities and the philosophy of occupational therapists in this regard.
- Programme development and design theory and processes, with a précis of the pedagogy of health education materials.

2.1 The Occupation of Mothering

There is a growing literature base which seeks to examine the role of mothering in human occupational performance.

Maternal work, which is not necessarily restricted to biological mothers, or even to women, is a function and role done by someone who sustains children and aids all aspects of their development.[10, 29]

Today, most mothering is still done by women[30] and a large portion of household and mothering tasks fall to women, even if they work full time.[29, 31]

Mothering is considered a mainstay of society, and is inherently valued because of the role that mothers are entrusted with - the creation of sanctuaries for their families, care and nurturing of children and as caretakers of a family's time.[10] However, in some instances, mothering also tends to be under-valued in society and not much research in the functioning of mothers is done,[31, 32] because it is 'unpaid' work,[31, 33] which is often not valued,[33] and because of its "commonness",[29] and invisibility.[26, 33] Mothering-work is therefore a paradox as it is both treasured and under-valued, with little research to understand its complexity and eventual effect on society.

Where studies have been completed into the manner in which mothers construct daily routines, the results have important implications for occupational therapists working with mothers.[10]

2.1.1 *The context of time and mothering*

In a qualitative study completed by Francis-Connolly (2000), the researcher found that mothers of young children were "immersed in motherhood" and had enormous demands on their time in an effort to care for their children. Based on interviews with 20 mothers of young children, the author used a modified grounded theory to develop themes. Words used to describe the mothering experience were 'overwhelming', 'intense', 'demanding' and 'unprepared'. The entry into motherhood is recognised as a time of major change in the psychology of a woman in and of itself,[30] without considering the changes to habit use, activity flow and comfort.[7]

A major theme emerging from the discourse is time management and a appreciation of the time it takes to get everything done combined

with the unrelenting nature of the job. Time can therefore be considered a resource or a limitation.[32]

Due to time constraints, mothers are often obliged to enfold activities (where attention is given to a number of goals in a single activity) in order to achieve many outcomes at the same time. Nurturing and care-taking take place at the same time as teaching, playing and emotional support.[29, 32] The simplicity of playing peek-a-boo while changing a nappy, masks the complexity of what is actually being enfolded into a few minutes. This, writes Francis-Connolly, is mothering.[29]

The coping strategies of mothers were examined in an interview based study of mothers with children with Attention Deficit Hyperactivity Disorder.[32] Mothers coped with time demands by making extensive use of enfolding of activities, but also showed polychronic time use – which introduces the idea of a priority in the focus of tasks. Mothers fit the tasks they need to do around child care.[32] This qualitative study is resonant of other researchers in the field, but lacks generalisation because of the narrow group of participants that were interviewed for data collection.

Conversely, 'unfolding' occurs when one performs one part of an occupation in isolation from a previously established routine of enfolded occupations. Unfolding is therefore more time consuming.[32]

Mothers more readily use enfolding in order to maximise their time, but use unfolding in order to improve the occupational performance of their children when necessary. They also unfold activities in order to play with their children.[34] The findings of this research should inform any potential development programme design. When activities are given that are essentially unfolding in nature, therapists need to find out if these are feasible with regard to the mothers available time resources.[35] Alternatively, given a mother's natural

proclivity to enfolding, therapists should try to provide programmes that conform to a mother's construction of her routine, and are enfolding in nature.[32]

The factors which influence the construction of daily routines, of mothers with children who had disabilities, were investigated by Hammon Kellergrew (2000) in her qualitative study.[21] Building on previous findings of her research, the author discovered that mothers created 'skill development time' within the ADL of their children, thus allowing crucial practicing time for skill development. They did this if the skill was emergent, if there was future value in developing the skill, and if there was time.[21] This is echoed in other research.[23, 24] Mothers made subtle daily adjustments in the routine to incorporate or exclude such practice time and as a result, children who lacked in a particular skill (for example getting dressed), had less opportunity to practice the skill over time as the mother took over the task.[21]

Eight thought processes were identified by the study conducted by Larson (2000) as being the basis of how mothers constructed their daily routines. They are "planning, organizing, balancing, anticipating, interpreting, forecasting, perspective shifting and meaning making".[34 p 273] Although the tasks of household management may be the same, each mother has to make changes based on their individual families and the child for whom the mothering work is intended.[21, 34] Further to the findings of how mothers create routines, was the emotional theme that highlighted that mothers' own sense of wellbeing was closely related to their success in mothering and in the orchestration of routines that allowed this.[34]

2.1.2 *Stimulation and play in the mothering time context*

If one dimension in which mothers work is time, another is space. A mother's use of toys and space in the development of an infant's skills was isolated as one component, within a broader study of infant-toddler spatial and temporal development, by Pierce (2000).[26] Interviews and video observations of mother-infant dyads from birth to 18-months of age were coded based on the grounded theory and yielded interesting results regarding mothering skills. The following are of relevance to this study:

The skills of mothers vis a vis which toys to present to their infants were more developmentally appropriate in mothers with other children. This suggests that the art of playing with an infant is learnt. Further, mothers used toys to engage their infants in order to allow them to get on with housework. Mothers consistently positioned their infants and the infant's toys in such a manner as to allow them to complete other work. Positioning devices were used almost universally across all levels of socio-economic strata. As such, mothers tried to reduce the need to be continually available to scaffold play.[26]

Mothers also determined where children may play, and these spaces were most likely to be adjacent to the kitchen as kitchens were where the mother's occupational activities were centred.[26]

Pierce (2000) also describes the home as a primary developmental space and highlights the invisible work that mothers do in making use of space, objects and time to support this development. It emphasises how important it is that therapists not de-contextualise intervention, but rather consider the spatial aspects of occupation.[26]

Similarly to the Francis-Connolly study (2000)[29] the extent to which this study can be generalised is limited by the narrow population used

in the sample selection. This was done in order to create homogeneity in the sample. The sample was spread evenly across socio-economic bands.[26]

2.1.3 *Therapy intervention programmes in the mothering time context*

Mothers also determined what activities to do within home programmes given to them by therapists based on a number of criteria. If mothers felt that intervention programmes robbed their infant of their babyhood, or put them in the constant role of 'therapist', they stopped them.[23] There had to be a sense of enjoyment for the child and mother in order for activities to be included in the daily routine. Most mothers created a mosaic of activities based on what they had learnt about an infant's early needs.[24] In the case of mothers of disabled children, these activities could be casually observed from a therapist, and the mother may not actually consider it to count as a home programme, but the activity would have been successfully assimilated into their routine.[24]

Although many of the studies examined were completed with mothers of disabled children, the conclusions reached can be extended to mothers of very young children, according to a study by Olson and Esdaile (2000).[33] They maintain that there are more similarities than differences between mothers who are at home with young children and those at home with disabled children, in as much as both groups are isolated and under enormous pressure.[33] They concur with the findings of Lawlor and Mattingly (1998) who outline the "Who is the client" dilemma.[36] Both research groups assert that if one focuses on the child as the client, half of the mother-infant dyadic co-occupation is ignored and the occupational needs of the mother will be compromised.[33, 36] As one mother of a child said: "*There is no time in my life that hasn't been spoken for, and for every 15 minute activity that is added, one has to be taken away.*" (p 78)[37]

> *"Insight into maternal work has implications for occupational therapy intervention. Serious consideration needs to be given to mothers' construction of daily life and the meaning of the mundane but essential routines that create a family's daily life. Dismantling or revising of daily routines for the insertion of intervention requires a deep understanding of family routines and their meaning to family members." (p 251)*[10]

In summary, in all of the studies presented, routine creation is a complex, subtle, often invisible process of accommodation and anticipation, and almost all of these studies indicated that time was a constraint to parents. These manipulations of routine can be considered wholly co-occupational within the dyad, but they constantly take into account the needs of the child over all. By virtue of the pressure of time, where a child is not able to complete a task, the opportunity to practice and master it is quickly lost in the demanding routine that mothers need to create.[21, 26, 29, 34]

2.2 Back to Sleep

2.2.1 *Sudden Infant Death Syndrome*

Sudden Infant Death Syndrome (SIDS) is the most common cause of unexpected, natural death of infants. Infants are most at risk between one and three months, and the risk tapers off toward the end of the first year.[13, 38]

Historically it was believed that SIDS only occurred when infants slept with, and were entrapped under, their mothers. This belief persisted until evidence became available of cultures where co-bedding was common and SIDS was rare.[38] Despite the common term of 'cot

death' SIDS can occur at any time of the day, but is most likely when infants are sleeping.[38]

Generally, there is a higher risk in infants who are premature. Some of the other risks for SIDS are related to environmental factors: Infants who co-bed with an adult who has had too much to drink, has taken sedatives, or smokes are thought to be at higher risk, as are infants who are placed to sleep on a couch or co-sleep on a couch with another person. Infants exposed pre- or post-natally to cigarette smoke have an increased risk.[38] Patterns of hyperthermia related to raised room temperature, excess bedding and covering the head, resulting in poor mechanisms for heat exchange are also thought to explain SIDS. Deaths are sometimes linked to respiratory illness in the infant's recent past.[4, 9, 13, 38]

In the mid 1980's the first research was published that suggested a link between sleep position and death, a link which has since been confirmed by a plethora of research.[13] In 25% to 60% of SIDS death scenes investigated, the infants were found prone.[12] Researchers and pathologists now delineate between infants who are found face down versus those who are found in a non-face down position.[12] Since the original call in 1992 for the 'Back to sleep campaign', the AAP has extended the risk factors to include side lying too, as there is a risk that infants will roll from side-lying to prone and asphyxiate.[13]

Bed sharing or co-bedding has become a contentious point in the debate and in the west is considered a risk.[38]

Current literature offers the following factors as being potentially protective against SIDS: supine sleeping, breastfeeding, use of a pacifier, omission of soft bedding and pillows, positioning the infant so that their feet are at the base of the cot, sleeping in close proximity to, but not with, parents and monitoring the temperature of the room.[13, 38]

2.2.2 *The "Back to Sleep" Campaign*

The Back to Sleep (BTS) campaign was launched as a parent education programme following the AAP directive linking prone sleeping position and SIDS.[4] Initially the information given to parents was to make use of the side- or back-lying position. However, when further research linked an increase risk for side-lying infants who rolled over on their own, the policy was changed to advise parents to use the back-lying position exclusively.[9]

Moon, Oden and Grady (2004) found that a 15 minute education session in the small group format was successful in educating parents regarding the risks of sleep positioning for SIDS, even in groups which traditionally had poor compliance with the BTS advice.[39]

Recommendations were extended to hospitals, as nursery staff could influence behaviour by modelling good positioning practices throughout the post-natal stay.[40, 41] Nurses in Neonatal ICU wards were encouraged to do this long before the discharge of premature infants as these infants are at increased risk of SIDS, but are often nursed in prone in order to facilitate breathing.[41]

Since the start of the BTS campaign a significant drop in SIDS rates has been observed.[13, 38,11, 42] Beyond the home environment, the programme has been adopted in day-care centres and crèches. More than 80% of facilities were aware of the BTS campaign, although just under 40% of them were implementing supine sleeping at the time. Fewer were aware of, or using the 'prone playing' corollary in research done by Selleck, Fergus, Berdar, Corriveau, Deltorto and Piazza (2003).[14]

2.2.3 *Effects of sleep position on motor development in Infants*

2.2.3.1 The effect of postural control and developmental delay:

Infant milestone achievement is discussed in the literature not so much in terms of dates as 'windows'. Ranges of normal milestone achievement have allowed for the natural variations in development that are seen across the world, and even within single population groups.[43] Variation must be allowed for in order to prevent premature diagnosis of delay. For example, the window for sitting unsupported is wide – anywhere from 3.8 months to 9.4 months. This sample presented a mean of 6.0 months and a standard deviation of 1.1 months or 35 days. The standard deviations reported in this study ranged from 35 days to 57 days.[43]

However, most standardised instruments to assess development place an individual on a continuum that is established by the testing of healthy individuals.[44] Normative standards are set and stratification provides a therapeutic cut off score.[45] These points are based on usual statistical tenets, and as such, one can make use of percentiles to determine when infants are at risk or in a deficit area.[44]

The criteria, used to adjudge whether a child shows developmental delay, vary within the literature and common practice. Within legislation in various states in the USA, a therapeutic cut off of $z \geq -1.5$ SD is affixed, or a child who is delayed by 25% or more in one performance area.[16, 46] Using this criteria, an infant from the WHO study (2006) who is 52 days delayed, or 1.75 months, should be considered for early intervention.

In South Africa, common practice is to use $z \geq -1.0$ standard deviations to inform eligibility for therapeutic services. Because there is no onerous application for funding (as is the case in the USA), any child presenting at a hospital with developmental delay of 1 – 1.5

months delay would receive therapy. No literature exists around therapeutic cut-off levels in the private sector in South Africa.

Therapists in early intervention are inclined to use narrower allowances for delay than the ranges described in the WHO study (2006)[43]. They carefully observe for functional application and qualitative movement deficits as indicators of possible problems, rather than a simple 'yes' or 'no' around motor milestone acquisition.[47, 48] This allows for early detection of problems, and the earlier therapy is started, in the cases of developmental delay, the better the outcome.[48, 49] Likewise, Jantz et al (1997)[5] noted that a motor assessment that uses a qualitative observation rather than just a milestone achievement scale is more appropriate when assessing the effects of motor delay, as the quality of the movement is evaluated.

Use of these testing cut-offs is based on the assumption that development occurs at a constant rate and delay at any one point will result in delays later on. Bartlett (2000) asserts that this is not the case and her quantitative, longitudinal study of 36 infants from 10-months through to 18-months demonstrated that infants who were delayed at 10-months were not necessarily deemed neurologically behind their peers at 18-months. In the sample at 10-months there was a number of outliers but by 18-months this scatter had pulled toward the mean.[50]

A comparison between the 10- and 15-month assessments indicated a link between locomotion scores at 10 months and the timing of walking, and infants who were delayed at 10-months walked as much as two months later than the non-delayed group. However, the Peabody Developmental Motor Scales -2nd Edition (PDMS-2) scores of both groups were within a normal range at 15 months and only one toddler, delayed at 10-months, continued to be delayed at 18-months

when tested by a paediatrician. The data therefore does not support the belief that a child who is delayed in infancy will continue to be delayed through toddlerhood.[20]

Bartlett (2000) does caution therapists from having a backlash reaction and missing neurological abnormalities. She concedes that subtle neurological damage can be masked in childhood and only present as clumsiness in pre-school years, and should not miss early identification and intervention.[20, 50] The message for therapists therefore is (in the absence of neurological abnormalities) to undertake serial assessments in order to establish a pattern of delay rather than one picture of functioning at a particular point in development and assuming that that point represents a pattern of delay.[20, 50]

Unfortunately, the study does not elucidate what criteria were used to determine the quality of the developmental skills at the time of the 18-month assessment, beyond describing the assessment as a 'standard paediatric examination'. This information would be useful in the light of studies by Majnemer et al (2006), which suggest that that the quality of movements in delayed infants may remain affected, even if a milestone has been acquired.[16]

The concern, when discussing delay within postural development, is that postural control is the central basis off which all motor actions take place. The stability of the musculature of the trunk determines to a large extent the ability of the individual to carry out age appropriate motor activities.[20, 47, 51, 52] Postural control is a dual function of the sensory and motor domains of the central nervous system. It is dependent on feedback from the vestibular, proprioceptive, visual and tactile systems, allowing a sense of the body in space and eliciting an adaptive motor response.[51, 53] Changes within the postural control system occurs across the lifespan, but are most easily observed in infancy as a progression of motor milestones.[53] Development of postural control has further links to

reaching skills, fine motor development, adaptive balance control and anticipatory postural preparation in a feed-forward mechanism of motor planning. Postural control may play a more important role than co-ordination as a predictor of sport participation in young children.[54] And problems in physical engagement in play are linked to social and educational sequalae which have a trickle-down effect on other areas of development.[54, 55] Preventing developmental delay caused by positioning choices is easier than remediation of the problem at later stages of development, or of long term consequences.[56]

Simpson, Colpe & Greenspan (2003) determined that the longer a child is delayed, the more encompassing the deficit becomes. In their study, young children (4 – 15 months) exhibited particular, functional delays, but the older toddlers (16 – 59 months) were more likely to present with a generalised delay.[48]

In order to test a hypothetical model of the interactions of early motor milestone acquisition and motor skill mastery in childhood, Viholainen et al (2006)[51] conducted a longitudinal study with 130 children from birth to 3.5 years as part of a larger study on dyslexia risk factors. Their data analysis of Movement-ABC scores obtained at three and a half years against developmental milestones logged in the first year of life resulted in the finding that early hand control in infants has a poor correlation for gross motor skills, but that early body control has a high correlation for manipulation skills. Hence, if an infant develops hand function skills earlier than body control skills, their gross motor skills are negatively affected. They speculated that this may be attributed to focus of attention; infants who are proficient at object manipulation may not need to move as much in their environment and so lose out on the practice time needed to challenge their postural control muscles.[51]

Their research also underscored the role of early intervention, confirming that early motor proficiency provides a good indicator for later motor skill. Therefore, early intervention for motor difficulties observed in infancy could improve later motor skill acquisition. The mediator between development in infancy and skill in childhood appears to be postural control. The Viholainen et al (2006) study therefore confirms the body of knowledge that asserts that postural control is the basis of motor development.[51]

There are other consequences to atypical development apart from just motor delays.[56] Shortening of the rhomboids, with external rotation of the shoulders and adducted scapulae, resulting from excessive supine positioning on a flat surface, can cause delayed self soothing, because of an inability to bring the hands to the mouth. This can have attachment and parenting side effects.[56] When an infant is consistently placed in supine they will begin to turn their heads consistently to one side, which results in precocious handedness, usually toward the right, and this can result in an inappropriate diagnosis of hemiplegia.[56]

Another debate which has been raised since the discovery of motor delays related to supine sleeping, has been the potential value of re-evaluating the norms provided for this current generation of children.[5] The debate to push developmental norms out a few months are rejected by Hunter and Malloy (2002), who call for medical practitioners to teach parents effective techniques to facilitate prone positioning, rather than loosing valuable exploration time for infants, the long term effects of which are not currently known.[56]

2.2.3.2 Discussion: The effect of supine sleeping on developmental motor milestones

Positioning an infant has a number of effects on the skeletal, muscular and behavioural systems. Applying sound positioning principles can be one of the simplest interventions to correcting

developmental problems, but a lack of attention or underestimating the effect of positioning that is unvaried, can have a detrimental effect on the infant.[57] Skeletal examples include positional plagiocephaly (flattening of the skull on the back or sides depending on consistent placement). Muscular examples include torticollis (shortening of the sternocleidomastoid muscle on one side with elongation on the other). Muscle shortening can occur rapidly if there isn't a variation in position and can interfere with behavioural organisation such as the ability to bring the hands to the midline.[57] The sequalae of these behavioural delays are fussiness, or the delay in learning to self calm.[56]

One example of a position overuse having an effect on development is the current examination of the effect of supine sleeping on motor development.[57] The effects are not merely linear, but have ripple effects in many subsystems of development.[58] It is believed that babies who sleep in prone would spend time just after waking up lifting their heads, pushing on their arms and generally practicing the movements afforded by the prone position, for as long as it took for them to get an adult's attention. This practice time was sufficient to make up for any positioning choices that mothers made after lifting them out of their beds. It is this prone time that appears to be in deficit for infants who sleep in supine.[56]

Early discussions on the effect of supine sleeping were presented by Mildred, Beard, Dallwitz and Unwin (1995)[19], who concluded that parents avoided the prone position for play following the BTS campaign. Thereafter, Jantz, Blosser and Fruechting (1997) observed delays, within a single private practice setting, in 4-month old infants who slept in supine. They concluded that sleep position should be taken into account when infant were assessed for motor delay and that parents' fears should be allayed by explaining that this could have an effect.[5] Dewey, Fleming, Golding and the ALSPAC Study

Team concluded that any delay noted at 6-months was transient.[59] One of the earliest attempts to quantify sleep position and the position used when awake was conducted by Davis, Moon, Sachs and Ottolini (1998).[20] A convenience sample of 400 healthy, full term infants were followed from birth to 18 months. Analysis of the log books, which parents completed, revealed that prone sleepers spent significantly more time in the prone position when awake than supine sleepers. The authors concluded that prone sleepers achieved their milestones earlier than supine sleepers. Supine sleepers were significantly slower to roll prone to supine, sit supported by one arm, creep, crawl and pull to stand. Although all infants walked within normal ranges, Davis et al (1998) concluded that this was not a necessarily an adequate indicator, since the infants who were delayed were typically delayed in areas that required upper body strength.[20]

A study which sought to investigate the effect of all wakeful positions on motor control touched on the effect of prone wake time. Bridgewater and Sullivan (1999)[60] made use of parent logs over three days before enrolled infants were assessed by blinded assessors. They concluded that infants with more active play time – in which they were handled in a playful manner through a variety of positions – benefitted developmentally. Playful bath time was also positively associated with head righting. Static positions were poorer positions in which to enhance maturation, with prone being better than supine or side-lying. The researchers concluded that the positions that involved close contact with caregivers, and great variation in position, such as bathing and playful handling resulted in the most mature responses within the postural adjustments of infants.[60] The study was conducted with a small sample, and was considered a pilot study by the authors. A larger sample size would be required before generalisation could be made.

In contrast to the finding of Bridgewater and Sullivan (1999), Salls, Silverman and Gatty (2002)[18] found no differences in 4- and 6-month-old-infants when using the Denver II Gross Motor Sector, regardless of positioning. However, there was a change in the progression of development, as supine sleeping infants rolled from supine to prone first. They noted that infants who spent 15 minutes or more in prone while awake were statistically similar to the normative data. This timing is based on parental estimates of the time their infants spent in prone.[18]

The first discussion around inappropriate therapeutic referrals for developmental delay was raised by Majnemer and Barr (2005).[15] Testing a control group of prone sleepers against a group of like-aged supine sleepers, the researchers found that, at six months, 58% of supine sleepers obtained a score one standard deviation lower than normal range for the Gross Motor Quotient (GMQ) of the PDMS-2. Increased supported sitting was negatively associated with GMQ scores and associated with raised Fine Motor Quotient (FMQ) scores. These findings are consistent with other research.[51] In the 6 month old group, the GMQ and FMQ means were almost 1 SD below the mean of a normative sample, and 22% fell below the therapeutic cut off of <78 for GMQ. This would warrant therapeutic intervention. When compared with the prone sleepers, there was a statistically significant difference in the prone raw score, supine raw score, total raw score and percentiles on the Alberta Infant Motor Scales (AIMS), and in the GMQ for the PDMS-2. With regard to long term delays, more infants were below the therapeutic cut off at 15- months in the supine sleepers than the prone sleepers.[15, 16] This research design by Majnemer and Barr (2005) also showed that parental recall of the amount of time an infant is in prone during the day is less than it really is when a Baby's Day Diary© is used.[16]

The role of supine positioning in psychomotor skill development was investigated by Vaivre-Douret, Dos Santos, Charlemain and Cabrol (2005)[61] They found that infants who lie in supine acquire psychomotor skills later than those who lie in prone and that the postural habit that is formed at birth tends to lead the organisation of motor patterns from birth to four months. This research was based on parent recall for detailed infant milestones. More recent research suggests that by 12 months, parents are not able to recall early milestones with accuracy.[62] Vaivre-Douret et al (2005) concede that many milestones for supine sleepers remained blank on answer sheets, but also argue that it is possible that parent did not recall these transitions because they weren't expressed. They found that deviations from normal developmental patterns were more likely to be observed from the supine sleepers. Supine sleepers were also more likely to skip dynamic/transitory skills such as crawling and were more passive about being moved or seated in a chair. The authors noted that there was the potential for implications for later development in terms of the quality of movement, and that there may be consequences of a psycho-affective and attention span that warrant longitudinal study of infants into their pre-school years.[61]

The negative relationship between supine sleep and motor development has also been confirmed among premature infants. Premature infants were always considered at risk for developmental delay because of their perceived or actual fragility, inherent physiological hypotonia and potential for neurological problems.[27, 56] Ratliff-Schaub et al (2001) confirmed that there is a link between supine sleep and motor delay in premature infants and this has been confirmed by more recent research.[63-65]

A similar study, conducted within a South African sample, demonstrated that supine sleeping infants were delayed according to developmental guidelines set forth by Bly.[66] Infants who spent less

than 30 minutes in prone a day and slept in supine, were significantly different to infants who slept in prone. This study also made use of parent recall for estimating the time spent in prone, and made use of a non standardised assessment, but the findings are consistent with the international literature that is available.[66]

In summary, the research conducted to date has highlighted that infants who sleep in supine are more likely to play in supine and to actively resist being positioned in prone. As a result they are not afforded opportunities to practice the movements this position encourages and are inclined to be delayed when assessed on norms that were created at a time when most infants were placed in prone to sleep.[67] However, these infants do catch up with their prone counterparts and all infants achieved their walking milestone within normally accepted timeframes.[67]

Little research has been conducted into the quality of movements that are achieved in the attainment of these milestones, however, and the potential long term effects on childhood activity levels, visual perception, motor proficiency and psychomotor skills should be examined.[16, 56, 58, 61, 67]

2.2.4 *Prone playing in supine sleeping infants*

The importance of using a prone position during play has been examined to reduce the cases of developmental occipital plagiocephally and torticollis, as well as motor delay. [9]

It has been found that infants tolerate prone positioning if it is introduced at birth.[56] By three months, the preferred sleep position is more or less fixed, and observations of infant-directed positioning show that infants prefer to play in the position in which they sleep.[61, 65] Therefore, since the BTS campaign should start from birth, infants

will quickly become averse to playing in prone, if it is not started early.[8, 18, 20, 56]

Bly (2000) indicates that the importance of the prone position is related to strengthening the extensors of the neck and back and the musculature of the shoulders, as well as being important for the development of rolling, creeping and crawling, unsupported sitting and pull to stand.[68] Tolerance of the prone position may be important in the development of bilateral integration because of the important role of rolling in development. Dissociation patterns are learnt through rolling. A paucity of prone positioning in awake time negatively affects developmental milestone achievement.[18]

However, parents and child care institutions alike place infants in prone to play for less time than is recommended and in some instances never put their infants down in prone.[5, 14, 16, 19, 69] There are many reasons for this. Fear may be a powerful motivator for parents not to use this position in play, as an over-extension of the warnings that they are given for sleep positioning.[8, 19] Prone is, however, a normal position in which to place an infant and they are at no increased risk of SIDS when supervised in this position.[9]

The problem of a lack of prone time is exacerbated in crèches, because research shows that infants there are more likely to be placed in a seating device, or to be held, than placed on the floor in any position.[70] Infants who sleep in supine and go to crèche are therefore the least likely to have prone playing time.

Less information is known about the effects of other infant devices such as car seats and baby chairs. Since they encourage the flexion position and bring the shoulders forward, they don't allow for the strengthening of the extensors, which is essential for developing the stability required for such weight-bearing positions as pushing up for reaching, crawling, pull to stand and standing.[47, 67] Bartlett and

Kneale Fanning (2003) found negative relationships with prolonged carrying or swing use and motor development.[65]

There is also a wide range of teaching regarding the amount of tummy time needed, and when to implement it during the day. Parents are seldom given any advice on how to help a baby who is resisting tummy time to become accustomed to that position.[8] In an information article provided to nurses, the importance of teaching parents to place their babies to sleep in supine was emphasised. The authors highlighted the important role that prone positioning plays in the prevention of plagiocephaly and motor milestone delay. However, the article did not provide any guidelines to nurses, regarding the amount of prone time necessary to compensate for supine sleeping. Rather, recommendations were that the baby be positioned in prone for short periods of time, two to three times a day. It was also recommended that prone play be started immediately post-nataly.[40]

In a quasi-experimental study, designed to determine whether brochure or video education campaigns were effective in teaching parents about the importance of tummy time, Jennings, Sarbaugh and Payne (2005) found that parents who received the brochure at 4-weeks, were already finding their infants resistant to being in prone. It was recommended that mothers receive the information as close to the time of the birth as possible.[8]

The effect of the brochure campaign is adjudged, by the authors, to have been successful, as there was an increase between phase I and II of the study in the number of mothers who incorporated tummy time into their daily routine, although the link between the brochure and the observed change in behaviour could only be inferred. The written document was considered to be a good means of conveying

information regarding prone positioning, including time frames and ideas for when and how to implement the programme.[8]

The result from the longitudinal component of this research contrasts other research in that it indicated that there was a significant difference between infants who were 'routinely' placed in prone more than once a day compared to those classified as 'not routinely' placed in prone by their parents. This difference was seen on the gross motor scores when the infants were re-tested at 18-months of age. Since parent recall was required in order to group the infants, it is not clear how accurate these groupings were, or whether the terms 'seldom', 'frequently', or 'routinely' were a sensitive enough delineator of prone 'dosage' in order to truly determine an effect on gross motor milestone acquisition.[8]

Prone positioning is not only based on parental knowledge and parenting trends.[28] It is also based on infant ability[21, 65] and preferences.[20] Following the early 'set point' of positions[61] which are comfortable and which allow for mastery of the environment, infants make choices as to where they want to be and vociferously make their preferences known.[20] Across a range of studies, mothers frequently reported that their infants didn't like lying on their stomachs.[8, 20, 61]

The efficacy of prone awake time and the exploration of the results of supine sleeping have received equal study by researchers, and are often reported in the same articles as a continuum of ideas. Various studies have examined the effect of 'no prone' vs. differing lengths of time in prone.[17] Infants, who spent awake time in prone, scored higher on the AIMS than their 'no prone' counterparts and these scores were statistically significant in all the subtests, except sitting and standing, in a study by Monson, Deitz and Kartin (2003).[17] This research design did not define time periods in prone, and the 'no

prone' group was defined as infants who were in prone "zero to once a day". As a result, it is conceivable that an infant who is in prone two or three times a day, but for only a minute at a time, could be compared with an infant who is placed in prone once a day, but for 20 minutes.[17] This makes generalisation of the findings difficult.

As a continuation of their examination of supine sleepers, Majnemer and Barr (2005 and 2006) found that awake prone positioning was still the most significant factor impacting on early motor development of supine sleeping infants.[15, 16]

A longitudinal study, conducted in order to determine the influence that duration and preference for prone positioning had on a cohort of infants at 4-, 6-, 12- and 24-months-of-age, showed that infants who spent more time in prone had earlier milestone achievement in incremental levels through the four groups.[62] Assessors were cognisant of the family preference for positioning of the infant when conducting assessments at 6- and 24-months. Few infants, in the three to four month window, spent more than 60 minutes in prone during the day and these were grouped into a larger group who spent ≥40 minutes in prone. Most infants in this window were either held or placed on their backs. In the 6 month window infants were more polarised, allowing only two groupings – prone and non-prone. The group that preferred prone wakeful positions represented only 16% of the sample. Data analysis of infants, who had experience in prone, showed that they rolled, crept and crawled (prone specific milestones) earlier than infants who had no experience in prone.[62] A threshold of 20 minutes a day in prone, elicited significant results. Delays found in the non-prone group in early infancy were transient. A cautionary note was interjected by the authors, as this transience may have been reflective of the nature of testing at two years – tests for gross motor competence tend to evaluate movements in sitting and standing and few tests look at antigravity control.[62]

Most of the studies conducted into the effects of supine sleeping and the efficacy of prone awake time made use of parent recall of the amount of time the infant spent in prone during the day.[5, 18, 62, 66, 71] This has been shown to be an inaccurate measure of evaluating said time.[16] Some studies made use of parent recall for milestone achievement,[20] without comment on the quality of movement, which may prove to be where residual difficulty persists.[16, 71] Few studies made use of a blinded assessor to evaluate infants' development.[16, 60, 71]

Despite these weaknesses in research methodology[67] used across the studies, the findings presented have been consistent. Generally it is held that infants who spend wakeful time in prone benefit developmentally.[5, 8, 17, 18, 20, 59, 71] Infants who did not, were found to be delayed at 4- and 6-months.[18, 20, 59] Those studies with a longitudinal component, found that the delays were transient and by 15- and 18-months, no delay was observable.[16, 18, 59, 62] However, long term research, continuing to preschool, is needed to determine whether there is an effect on motor activity levels, concentration and motor planning later.[16, 18, 27, 61] Assessments also need to determine whether there is a qualitative variation in the manner in which milestones are achieved, rather than a simple yes/no adjudement.[16, 18] Research in this area whose methodologies are rigorous, have been conducted with small sample sizes and therefore lack the ability to be generalised.[67]

2.3 Occupationally embedded exercise

The concept of occupationally-embedded exercise is currently gaining popularity as various theory bases confirm the basic tenet of occupational therapy,[2] which is that change and recovery occur through participation in the everyday activities which make up life.[53, 72] Practice outside of normal life can be meaningless to a client.[73]

Many survivors of trauma and illness actually figure out how to recover, by themselves, once they are released from rehabilitation facilities and have to live in the context of real life again.[73] This knitting together of occupational science and therapy has the following factual basis:

The advantage of embedded exercise over rote exercise has been shown to be that the development of skill occurs naturally in the pursuit of a goal. Occupationally-embedded activities are part of the narrative, the story-telling daily life, and are put in because they enhance the story.[73] They are part of a plan of recovery or prevention and the client therefore is motivated to persevere.[74] In order for the control to be in the hands of the client, they need to know what they are doing and why and how that activity will add meaning to their life. Rote exercise does not do this unless the client is motivated by exercise for its own sake.[2] Further, activities themselves guide and shape movements around tools and objects, thereby producing a skill and eliciting exercise. As a result, it does not result in the training of a single movement, but rather co-ordinates the transitions between multiple movements and postures within the environment. The multi-dimensional nature of the activity may provide other non-motor benefits – sensory pleasure, cognitive feedback and social interaction – which act as motivators throughout the task and in the case of developmental goals, provide multi-layered developmental opportunities. These are motivating in themselves and therefore become internal or intrinsic and do not depend on an external force coaxing for a 'little bit longer, a few more steps". It is possible that one will tolerate the discomfort of a movement or exercise for longer and perform it more smoothly if distracted by the activity in which the exercise is embedded, whereas rote exercise, not being intrinsically motivating, may be stopped when discomfort is perceived.[2]

In a meta-analytic review of occupationally-embedded activities, Lin, Wu, Tickle-Degnen and Coster (1997) concluded that motor performance is indeed improved when participating in naturalistic occupations. Objectives or tools within occupations should shape and direct movement towards a goal that the subject finds motivating. This in itself possibly results in a smoother, more controlled movement as the conscious focus is on the goal and not on the movement.[3] The key feature of occupationally-embedded activities is that the meaningfulness of the task is maintained and therefore motivation is maintained.[3] There is also more carry-over of skills than is observed in decontextualised exercise.[75]

The term 'activity focused interventions' is used by Valvano and Rapport, in the same manner that Nelson makes use of the term 'occupationally-embedded activity'. They essentially apply the benefits of occupationally-embedded activity to the daily routines of infants. Although the infants in their study have neurological conditions, the application of occupationally-embedded activities will affect the parenting skills of their mothers, and these can be generalised to mothers of small children. The activity focused intervention programme is designed using principles from motor learning theory and motor development theory, and is based on activities within the family daily routine. Important components are repetition and problems solving so that the skills are generalised across many actions. For this reason, the programme isn't prescriptive because the newness of each day and different contexts is a tool in itself.[72]

One way in which a disruption of a role, such as the shift to motherhood, creates stress is that it results in increased energy expenditure being necessary in order to try to consciously plan, that which was previously smooth or unconsciously executed.[7] By embedding one activity into another, which was previously known,

energy expenditure can be reduced. This allows the mother to recreate a flow of activities which is once again, seamless and comfortable.[7]

2.4 Programme Development

In the development of an intervention programme, background study into the basic biological processes is necessary.[76] An understanding of the underlying framework and principles is important. This groundwork is informed by what is already known about a particular biological process, occupational pattern, or deficit and is directed by the notion held by the investigator as to what the problem/solution may be. A theory as to the intervention is created, and measures are identified or created to determine change of the dependent variable.[77] Thereafter a process of testing and refining should be entered into before one can legitimately say that a programme has been developed.

The use of randomised controlled trials, rather than case studies or anecdotal evidence, does not have a strong historical standing in occupational therapy. This is a process that is necessary, in the context of evidence based medicine if occupational therapy interventions are to be considered credible and adoptable. Fortunately, this historical gap is changing.

2.4.1 *Principles for designing family centred programmes*

This programme was designed based on the principles of family-centred care.

The concept of 'Family centred care' has really grown out of the Early Interventionist Model of providing therapy services for disabled infants and children.[49, 78, 79] Even when the programme is preventative in nature, and no pathology is observed, we have moved

away from the mindset that the delayed or 'at risk' child is the client in totality.[79, 80] A key concept that resonates with this study is that the child's care is actually a part of the parent's ADL. Therefore the programme – if it is not to place additional stress to a parent's schedule – should be within the tasks with which the parent is routinely engaged. Advice to parents, should therefore be non-didactic, and should encourage parents to observe their child and intervene, rather than depending on a child care professional to intervene. This strengthens the parent-child relationship and often results in more sustained, generalised improvements for both parties.[79] A non-didactic approach teaches a mother principles of intervention and how to adjudge for herself whether they are working.[25] The locus of control is left with the mother, as the expert on her child,[81-83] throughout the process, and her own expertise with her baby is emphasised and facilitated. In this way the mother, not the therapist, is the mechanism of change.[83] The therapist is a collaborator and a large part of the success between parent and therapist is the relationship that is built on the flow of information.[25, 78, 81, 83]

In order for a programme to be embraced by a mother or family, the family needs to have identified it as being a necessary change and the process of implementing it needs to have functional importance and also needs to be easily enfolded into family life, as has been discussed in the literature review of 'mothering'.

The intervention programme also needs to allow for skill practicing through repetition in order to become habitual and automatic.[35] Another principle in the programme design, drawn from the family-centred model of intervention, was that the focus should be on changing the environment to best enable the child to develop, rather than focusing on the child's movement and stopping any so-called abnormal patterns. In this case, it may refer to the early

development of hand skills. Rather than stop the infant from focusing on objects in their hands, environmental changes can be used to rather encourage the exploration of space and movement and allow the infant chance to spontaneously discover a different path.[72]

The family-centred therapy model also informs the evaluation of the programme. In acknowledging that parenting is a deeply personal experience, and a parent's own resources are brought to bear on the work of parenting, therapists acknowledge that not all parents are going to respond in the same manner to an intervention programme and therefore, non-implementation can't be judgmentally considered in the light of 'compliance'.[82] The language of 'non-compliance' holds no place in the family-centred model. There is an unspoken cultural expectation for people to comply with programmes that reduce their health risks. However, the aim of a prevention programme is not to medicalise life, but to focus on living and wellness, which occupational therapy seeks to do.[84] Parenting should not be given over to the control of experts who tell mothers what is good and what is not.[85] Hanna and Roger (2002) hold that the success of a programme should be evaluated by asking questions about parent stress, and ease of implementation, rather than by measuring developmental improvement.[82] In this study, the *effect* of the programme was in question, but to answer questions about the *success* of the programme, focus groups with mothers would have needed to be run.

2.4.2 *Theory base of the IPCP design*

The programme design process was initiated with a background study of motor development and an investigation into the mechanisms of change underpinning the observable process of maturation. Detailed descriptions of infant maturation are to be found in abundance. Insight was gained from a number of sources,[47, 58, 68, 80, 86-94] each of

which contributed to a further understanding of what was considered 'optimal' for this age span.

Initial studies by theorists such as Gesell (1940)[95 cited 58] and McGraw (1943)[86] attribute development to factors such as muscle strengthening and cortical maturation. The observable succession of development occurs when a 'better' method of achieving a goal is uncovered, with an underlying assumption that this progression toward the 'optimal mature state' was somehow hard-wired into the individual. This allowed for predictability, despite variation and differences in culture and individuals. The notion was that there were some significant phases in the development of specific motor functions that act as the 'key' in unlocking the means to move.[86] These were qualitatively observed, and acted as the precursors to a motor milestone. They develop simultaneously, but unlock movements in sequence. For example, McGraw (1943) hypothesises that 'rolling' is in evidence from birth. Initial movements are not systematic or functional, but changes in muscle tension in relation to reflex activity and the effect of gravity can result in an infant appearing to roll. Turning of the head or shoulders to see or to reach, but no functional rolling (phase A) is seen as a progression toward (phase B) arching the head and back into extension and pushing the pelvis over the underneath leg, followed in a log by the shoulders, to effect a roll. This manoeuvre is not terribly effective because the infant can just as easily tip back to the starting position, so as muscle strength and further motor control is gained (encompassing phase C), the infant rolls with deliberation (phase D). McGraw saw a significant amount of overlap in these phases, such that parts of phase A and C can be seen together, and at about 300 days of age, phase B is waning and phase D is waxing.[86]

This construct by McGraw is held across many developmental theories such as cognition and perception. Theorists attribute development to

factors such as muscle strengthening, neural development and myelinantion. Motor development is considered to be sequential, progressing in a cephalocaudal direction, from proximal stability to distal control. Postural control is seen as a precursor to movement and is the balance between mobility and stability.[53] This provides the platform upon which more organised or skilled movement occurs.[80, 96] All of these theoretical constructs assume that the end-point is innate, with the components present at birth, but 'waiting in the wings'. This has provided a robust nature vs. nurture debate. [53, 58]

However, biology is not supportive of this reductionistic thesis.[58] What is known about neural cell proliferation, migration and myelination insists to a certain extent, that the foetus is indeed a *tabula rasa* – a blank slate – and a certain amount of self organisation is required for behaviours to become established.[58, 97]

A more recent construct is the dynamic systems theory. This theory base states that it takes more than just muscle strength or neuronal maturation to produce motor advancement.[58, 81] The theory is that multiple systems, both intrinsic and extrinsic to the infant, interact *in the context of a task* to produce behaviour.[80, 81, 98]

This alternate view, Thelen and Smith argue, provides a more multifaceted concept of development.[58] When viewed from a distance, the development of normal individuals has the appearance of a neat, linear conformation to an unseen code of rules, inevitably sequenced and predictable. When zooming in on the details though, the start and end become inextricably linked with multiple systems, biological properties and the context in which the individual is learning. Opportunities used and opportunities missed create messy cycles of function, achievement and exploration. From a starting point at birth, each system develops on a trajectory that is strangely dichotomous and concurrent, independent and interdependent,

dynamic and yet seeking stability. In the end, the set of 'rules' created must be malleable and sensitive to change in order to allow adaptability and context driven variation. The result is a web, rather than a process, of development[58] where the law of unintended consequences can be observed, as a small change in one subsystem can have an unexpected effect on another system, showing itself to be a heretofore unknown factor.[81]

As such, some factors can become rate limiting,[58, 81, 91] as Thelen and Smith (1996) have demonstrated in a study of infant kicking and stepping behaviours. They concluded that the loss of stepping at around 7 months in infancy is related to the ratio of fat to muscle in the infant, and not, as previously thought, to a phasic thesis[86] related to neural development and the extinguishing of behaviours. Thelen and Smith (1996) critique McGraw's work as being a panoramic sweep of progression, yet flawed in that the only explanation for progression along the patterns was 'cortical maturation'. Further, what began as a *description* was equated at the time as a *process,* a maturation driven phenomenon that resulted in species specific outcomes. In their summary of developmental theorists, Slater and Lewis (2002) concur, pointing out that numerous other factors need to be taken into account.[91]

Within the dynamic systems theory of development explanation a principle of stability and instability is noted, with neuroplasticity and exploration working together to create transition phases between stable motor patterns and emergent patterns, and in these windows an opportunity exists to intervene in the pattern of development.[81] Because movement is initiated for a reason, interventions will be most successfully inserted at such a time and in such a manner that assists the child who is trying to attempt a new task.[72] This is a basic tenet upon which occupational therapy stands.

Using the dynamic systems approach to motor intervention resonates with occupational therapy because of the emphasis on normal activity within the context of life, where motor advancement is unsurprisingly best learnt in daily routine.[2]

Any programmes in this area therefore, are most successfully adapted when drawing from dynamic systems theory[58] and motor learning theory[53] and what is known of the sweep of development,[47, 91] with motor practice structured within activities in such a manner that repetition and problem solving provide an easily generalised skill.[72] For this reason, a programme cannot be prescriptive or rote, because of the variation in daily living[2, 7] A key factor to this is self-movement – passive movement does not have the same training effect.[72] In the case of young infants, little purposeful movement is seen and movements against gravity are the main area of mastery that is expected in this age group.[80]

2.4.3 *Health education materials*

A core philosophy of occupational therapy lies in education of clients in such a manner as to empower them to make good choices.[74] But there is a sentiment that the process of finding the best manner to teach a client a programme, is best left to experts in pedagogy. Therefore, simple rules and insights into the best teaching method for the programme were sought for the fulfilment of this design.

The basic principles that are encouraged in the literature on health education materials, are that the information brochure must be credible, useful and adoptable. Written text needs to be evaluated for readability, which is "the ease with which material can be read"[99] and if possible a readability score calculated for the content, for example the Flesch-Kincaid Formula.[100] Documents produced on a computer, can calculate their own readability score.[101] Readability scores are based on the number of words per sentence and the

average number of syllables per word. Results are expressed as grade or age based reading levels, depending on the test.[100]

Most therapists used written information to supplement verbal teaching and provide the written information in order to help their clients to remember what had been said.[102] Parents prefer a combination of approaches to convey information – written information, verbal explanations and demonstrations of the motor pattern required.[23, 103]

Literature in this area recommends that words be typed in font size 12 or larger and that a limited number of fonts be employed. Text should be graded at a Grade 9 (USA) reading level (i.e. the wording would be readable by a child who has had 9 years of education and is 14 years old),[104] although other sources recommend that it be lower - at a Grade 5 or 6 level.[99] It is important to reduce sentence length and to limit technical or anatomical terms, in order to improve the readability of the document.[104] The use of illustrations significantly improves the comprehension of a piece. Stick or line drawings are considered difficult to interpret. With appropriate illustrations, 'poor readers' have a better comprehension of a more difficult written piece than they would have experienced without them.[105] These illustrations need to be next to the text they elucidate. Text should be presented in the present tense and in a manner that encourages positive decision making.[104] Of further importance is the emotional tone of the presentation. Information that evokes a positive emotional response is more likely to be accepted and remembered.[106] A language tone that is coercive does not empower a reader to make informed decisions to their benefit, nor does it imbue a sense of the reader being in control.[85] Of particular importance in conveying information to a parent, such that the family centred approach will be maintained, is conveying the message that the parent is in charge of the process, and that the information and techniques are really just

tools which the mother uses to achieve her goals and she herself is the mechanism of change.[83]

2.4.4 *Conclusion*

The IPCP was therefore designed based on a wide range of subjects, including the normative data of what can be expected from an infant within these months, and combining these with the principles of family centred programme development. The medium of disseminating this information to parents was through written brochures, and the guidelines for forming this health material informed the process of designing and wording all information. In the end these three components could be drawn together to create the educational programme.

CHAPTER 3 PROGRAMME DEVELOPMENT AND RESEARCH METHODOLOGY

This study was divided into two parts.

Part A (represented in green in Figure 3.1) – to design and validate a programme to improve motor development of infants that could be incorporated into a mother's ADL.

Part B (represented in blue in Figure 3.1) – an experimental research study to establish the effect of the programme on motor development of infants who do not sleep in the prone position.

Figure 3.1 Flow diagram indicating the process of the study, indicating Part A (green) and Part B (blue)

Part A: Programme Development

The first part of this chapter will discuss the development of the postural control programme, the rationale for activity inclusion and the process of creating a photo sheet to provide visual prompts for mothers as they carried out the programme.

3.1 Programme design

The programme was designed using the understanding of normal development that has been summarised in the literature review and holding to the principles of family centred care. The theories surrounding the manner in which mothers construct their daily routines was referred to consistently in order for the programme to be sustainable. The programme was therefore designed around the premise that the activities used must be part of the normal tasks of the *mother* and a natural part of her interaction with her baby.[29, 34] It is therefore multi-systemic, and is intended to support a new mother who is making the transition to the roles and habits and occupational performance of 'motherhood'.[7, 84, 107]

A summary of what was considered 'optimal' for this age span was incorporated on the activity sheets created for the purposes of brainstorming activities. (Appendix A) Activities that could be useful to challenge prone positioning, were then brainstormed. This creative process considered any number of parenting tasks and whether a 'tummy time' activity/posture/movement could be inserted into it. Activities of daily living for most mothers in the early months of their infants' lives revolve around baby care such as bathing, feeding, consoling and interaction, household management such as cooking, cleaning, and laundry, and also extent to leisure, social and personal management pursuits which existed before the birth of the baby. Many of the activities/postures for mothers to do with their baby were

adapted from activity ideas prescribed for developmentally delayed infants.[87, 108] Some ideas were inspired by the Motor Activities Programme of the PDMS-2,[109] others were from personal experience.

From this brainstorming process, a list of activity ideas that would form the basis of the Infant Postural Control Programme (IPCP) was created, with considerations for position, grading and uses. (Appendix A)

The underlying philosophy adopted during this process was to 'de-medicalise' the programme. The use of the mother's own body and everyday activities, combined with ideas that would resonate as common sense was deliberately used to enable the mother to own the process of stimulating her baby's growth.[84, 85]

3.2 Postural Control Programme Validation

3.2.1 *Content Validity*

3.2.1.1 Pilot study 1: Initial Activity Validation

Initial versions of the programme were sent, in written format with sketches of positions, to a panel of four experienced therapists to validate the content.

Panel selection

Two occupational therapists and two physiotherapists, all of whom have particular interest and many years experience in the treatment of infants and young children, were approached to participate in the initial pilot study.

Inclusion criteria

- 10 years experience the treatment of infants and young children,

- and/or post-graduate qualification

in order to qualify as an expert for validation purposes.[110]

After the panel had had a chance to look at the initially proposed programme, an individual interview time was arranged and the therapists were able to comment on the activities.

At each interview, comments related to suitability, safety, appropriateness and applicability of the activities, were garnered. The therapists rejected structuring that they considered too specialized and those that they anticipated would be better taught in a one-to-one session by a therapist. Water play activities were discarded because of safety and liability factors. The therapists gave advice regarding grading of activities and often moved structuring to a later age or started a movement in a more controlled manner at an earlier age. Their input regarding key teaching points, facilitation techniques and ideas for activity progression was invaluable. Generally the advice given helped to simplify the task for parents. They also brought their experience to bear on how best to teach parents' various handling concepts.

A complete list of the original activities, including those which were discarded, and a compilation of the expert's comments is available as Appendix A.

Where the advice of the therapists was in conflict, the advice of the most experienced therapist was taken as the decisive authority.

3.2.1.2 Pilot study 2: Interim Activity Validation

Following the initial comments, a second draft of the activities, in written form, was sent to the panellists who were prepared to continue with the programme beyond the interview stage. The revised panel of experts consisted of one occupational therapist and one physiotherapist, who had previously assisted during the first

iteration of content validation. Once the therapists had seen this final draft and approved the content, the programme design was finalized and the production of the photo-sheets, as well as the nurse's training manual was started.

3.3 Photo sheets

3.3.1 *Photo Sheet Design*

The process of creating meaningful, instructive photo-sheets that would accompany the training given by the nursing sisters was undertaken as part of the programme design. It was considered important for the photo sheets to be a simple reminder of the activities that the nurses had taught when the mothers returned home, and also provide a teaching tool for the nurses.

Verbal permission was obtained from each mother who participated in making the photographs, with her baby. It was made clear at the time that the purpose of the photo-sheets was for a research project. Should the programme be published in the future, written permission would be sought from the mothers to allow their photographs to continue to be used.

The photographs were taken with age appropriate infants known to the researcher. The infants were posed with their own mothers, in their homes, so that interaction and activity participation could be conveyed. (Figure 3.2) This was also a process of trying the activities with a 'lay person'. Each of the mothers photographed was taught the activity as the programme defined it and photographs were taken of the real-life execution of these activities.

Figure 3.2 Pushing up on arms and reaching in natural play

The photo-sheet layouts were compiled in conjunction with a graphic designer. The intention behind the designs was for them to be fun and not at all prescriptive – rather to give a variety of postural and structural suggestions. As such, some of the principles of health education material[101] were ignored– for example, the amount of white borders showing - but guidelines regarding font size and readability scores were followed.

Figure 3.3 Snapshot of PDF file, Photo sheet page 1

Some common elements and headings were held across the different months, so that the mothers could see how certain postures and activities were being upgraded on a monthly basis to provide a more appropriate challenge to their infant's development.

For example, short periods of time spent on the baby's stomach after nappy changes were carried across progressive pages, with suggestions of how to support and entertain the infant in these positions as their tolerance increased. Then at five months a progression was made to have the stomach time on the floor rather than the change mat/compactum for safety reasons. This is indicated in the photographic 'story' that is being created.

Another common thread is the use of similar headings for each upgraded activity. Likewise, arrows are used in a consistent manner, to indicate facilitatory points of control and handling techniques or cautionary notes.

In total, ten photo-sheets were created, with two pages each for:

- two to three months (Appendix B 1 & 2),
- three to four months (Appendix C 1 & 2),
- four to five months (Appendix D 1 & 2),
- five to six months (Appendix E 1 & 2) and
- over six months (Appendix F 1 & 2).

The final sheet was created to be a maintenance programme in case there was a delay in reassessment of the intervention group infants, for logistical or circumstantial reasons.

The photo-sheets were divided into age bands in order to provide structure and a starting point for the nurses, however, they could

also be used flexibly and if an infant was not managing an activity at their age level, the previous photo-sheet could provide reference and grading.

3.3.2 *Pilot study 3: Final Content Validation*

To validate the content and acceptability of the photo-sheets, they were forwarded to one physiotherapist and one occupational therapist who had assisted in the previous stages of validation of the programme.

Comments regarding the applicability of the pictures, ease of understanding and therapeutic factors, such as correctness and safety were invited. Suggestions were then incorporated into the photo sheet design, with the main changes relating to specific handling points.

These two therapists continued through the process of making the photo-sheets, providing critique of the photographs and layout as it pertained to text and labels of facilitation points for the parents. Several interviews, with each therapist, were held through the process of making the photo-sheets to ensure the faithfulness of the photo sheets to the original programme. This continued and intensive interaction ensured content validation was an ongoing process until the photo-sheets were finalised.

Figure 3.4 Initial facilitated sitting

Figure 3.5 Corrected facilitated sitting

As an example of the process these photographs are provided. The therapists felt that the early photographs, (Figure 3.4) might have been misinterpreted to suggest that the upper arm of the baby is facilitated by pulling it because of the position of the mother's hand, and so it was suggested that that photograph be retaken with more overt guidance of the trunk, as it is in Figure 3.5

Since arrows were used to show the mothers where to place their hands to facilitate movement, these could be moved, at the

prompting of the expert therapists, to be more specific or helpful. Other changes addressed terminology of the instructions to reduce the amount of text on the sheets, but to maximize the message conveyed. Some changes to activity structuring occurred on a few of the latter pages and photographs were retaken with a different infant in order to ensure that the infant in the photograph was still appropriate age. This served as a sifting process too, as one activity in particular (a play position with the mother lying on her side on the floor and the infant using her body for support in upright kneeling) looked awkward, no matter how many pictures were taken, and it was therefore excluded. (Figure 3.6)

Figure 3.6 Rejected Position

Part B: Research Methodology

This section describes the study design, the study population, as well as describing how the sample was selected and how data was collected. The methods used for data organisation and processing are also clarified.

3.4 Study design

The design of the study involved a quasi-experimental comparison between groups of infants that were treated using the IPCP and those who were not. It involved 13 Well Baby practices at which babies who slept supine were recruited into either a usual care or intervention group. The IPCP was then given to the intervention group to address the time in the prone position.

The study was a quantitative comparison and can be considered quasi-experimental because the individuals enrolled could not be randomly assigned,[45] but had to be assigned by cluster. Thus Well Baby clinics chosen for this study were assigned to either an intervention group or a usual care group. Seven clinics participated in the intervention group, while six served as a usual care comparison. Practices were randomly assigned as either intervention or usual care, and cluster samples of mother/infant dyads were drawn from their client base.

The aforementioned approach results in a less rigorous investigation, as extraneous factors, such as the personality traits or teaching skills of the nurses, could impact on each group. However, cluster sampling was the most practical means available to prevent contamination of the sample due to mothers comparing what they had been taught at a clinic.

The research required at this stage of programme development was a small, exploratory trial (Phase II)[77] which would provide a controlled investigation of the efficacy of the intervention.

There is a single categorical independent variable being tested, namely the developmental programme (IPCP), embedded into the ADL of parents.

The study design was also a blinded study, as the researcher was not aware of which group the infants belonged to either at baseline or at follow-up assessments. Blinding was maintained through the use of codes until after the data was analysed. Codes were assigned to infants by a research assistant.

3.4.1 *Study Setting: Well Baby Clinics*

Nursing sisters at Well Baby Clinics were a natural source of information regarding stimulation and infant development. From the time of birth they saw the parents on a regular basis until the infant was a year old. During these routine visits they gave vaccinations, weigh the infants and provide advice regarding feeding and nutrition. They were a normal conduit for information that is pertinent to development and stimulation. As such, mothers perceive the information as being reliable.[111]

Conversely, the referral of a young, normally developing infant to a therapist may seem alarming to a mother. It was for this reason that the Well Baby clinics were chosen for the study setting.

3.5 Study Population and Sample Selection

The study was conducted using a sample from a population of parent/infant dyads involving typically developing, healthy infants, who were placed in a supine position to sleep and were between 8 and 28 weeks old.

Nurses were recruited to assist with the identification of suitable, normal, supine sleeping infants whose parents would be recruited to take part in the study and also the dissemination of the IPCP in the case of the intervention group.

3.5.1 *Selection of nurses at Well Baby Clinics*

Convenience sampling was used whereby maternity wards in private clinics in the northern suburbs of Johannesburg were contacted and asked to whom they referred mothers to following discharge from the unit. All the clinics provided the names of nurses to whom they routinely referred the mothers, or the name of the paediatricians who had nurses at their offices.

Initial contact was made with all referrals, at which time the aim of the research project was explained. Follow-up appointments were made with the nurses to further explain the research and to determine whether they would be prepared to participate. On occasion the nurses knew of others who they felt may be prepared to participate and contact was made with them too, thus using snowball sampling.

Private Well baby clinics were adjudged to have a higher consistency of return visits, than clinics held in pharmacies or municipal facilities, as nurses operating their own practices are more likely to try to establish a relationship with their clients. This relationship building is a positive factor in trying to reduce attrition of the sample.[112]

Furthermore, in limiting the practices used to those who charge for their services, the likelihood of the several inter-related influences that poverty has on motor development is reduced.[48, 55, 113] Municipal and government hospitals in South Africa serve a wide variety of socio-economic groups, which introduces a wide range of complicating factors. The assumption was also made that mothers

who were prepared to pay for a service have a certain degree of health literacy, and were persuaded that the service and advice was valuable.[100]

The following formed the basis for the inclusion or exclusion of nurses from the Well Baby clinics:

3.5.1.1 Inclusion criteria:

- Nursing sisters who saw infants for their postnatal vaccines and weight follow ups were included.
- Nursing sisters who agreed to participate.

3.5.1.2 Exclusion criteria:

- Nursing sisters who were not providing advice to mothers based on the principles of the "Back to Sleep" campaign.
- Nursing sisters who were not prepared to be trained in the postural control programme.
- Nursing sisters who were not potentially able to fit teaching of the programme into an appointment (that is, if their appointments were routinely very short).

Four of the nurses at the 15 Well Baby clinics that were contacted, declined to participate. Two others agreed initially to an appointment, but then could not commit to a time and so contact was lost. In the end the nursing sisters at 10 clinics agreed to participate and signed a consent form (Appendix G).

During the weeks of parent enrolment it became apparent that the nurses were finding it difficult to secure the mothers' participation. It appeared that the mothers were reluctant to commit to the programme for a long time period. A further three practices were therefore approached and agreed to become involved.

3.5.2 *Selection of Mother-infant Dyads*

It was intended that each practice would ask all the mothers of eight week old infants whether they would be prepared to participate in the project, until such a time as five mothers and their babies had been enrolled per clinic. This would have resulted in a sample size of 50 mother/infant dyads (25 usual care, 25 intervention). This is the statistically determined sample size required to detect a difference between the groups, working at a 90% power and a 0.005 level of significance when testing on the Peabody Developmental Motor Scales – 2nd Edition (PDMS-2).

Consent forms for the study were signed by the mothers and left with the nurses (Appendix H and I). In order to improve the rigor of the study nurses asked all mothers, presenting at their practices for their first vaccinations, to participate. They did not purposefully select candidates who appeared more co-operative or sympathetic to the subject matter.

The following inclusion and exclusion criteria were used, in order to select mothers from the appropriate population:

3.5.2.1 Inclusion criteria:

- Mother/infant dyads of healthy, 8 week old infants who slept in supine or in side-lying position 90% of the time,
- Mother/infant dyads who were willing to participate in the study
- Mother/infant dyads where the infants were considered to be typically developing if the attending parent reported that this was the paediatrician's finding at the infant's 6 week appointment.

3.5.2.2 Exclusion criteria:

Infants were excluded from the study if

- The infant was born before 37 weeks gestational age,
- The infant had had any reported illnesses or prolonged hospital stay that may have resulted in developmental delays or neurological insult,
- The infant had any orthopaedic, muscular, neurological, genetic or metabolic conditions that may have affected motor development,
- The infant was placed prone to sleep or if the sleep position inconsistently included a combination of prone and supine sleep positions,
- The mothers were unable to complete the diary and questionnaire for language reasons,
- The mothers intended to attend a mother/infant stimulation group which addressed motor development during the duration of the research.

3.6 Ethics

Ethical clearance was granted by the Committee for Research on Human Subjects, University of the Witwatersrand, Ethical Clearance certificate number M070831 (Appendix J).

The parents were assured of the following when they were initially approached:

- Participation was completely voluntary and they could withdraw at any time.
- The services from the clinic would not be changed or negatively affected for those parents who chose not to participate.
- The contact details and names that were needed, in order to facilitate the assessments, would be held by the researcher only.
- The list that linked names and research codes would be held by the research assistant only. This was the only list that linked the infant with the raw data.
- In the event that any of the infants was significantly developmentally delayed, feedback would be given to the parents and recommendations regarding follow-up would be made.
- Also, participants who requested feedback, would be given the results of the assessment.

The information sheet provided for nurses and their informed consent is provided as Appendix G.

The information sheets for the mothers and their informed consent appear as Appendix H and Appendix I.

The Biographical Questionnaire completed by all parents is included in Appendix K.

3.7 Research Procedure

3.7.1 *Randomisation of clinics*

Clinics that were enrolled in the study were randomly assigned to the usual care or intervention groups by means of a randomization

table.[44] Since 10 clinics/nursing sisters agreed to participate initially, five practices were randomly assigned to the intervention group cluster and five to the usual care group cluster. When three additional practices were recruited, two were randomly assigned to the intervention group cluster and one to the usual care group cluster. Although a total of 13 clinics were involved, functionally, there were only six control practices and five intervention practices as two of the nurses failed to enrol any mothers at their clinics.

As a result, all the mother/infant dyads at a given practice were in the same group creating a cluster sample of infants. This was done in order to prevent cross contamination between mothers at the same practice and to reduce the possibility of the sisters at the clinics accidentally providing the incorrect intervention to parents in different groups.

3.7.2 *Training of nurses*

Nursing sisters from the Well Baby clinics assigned to the intervention group were trained in the IPCP in order to teach the intervention. It was initially planned to train all of the nurses at one training session so that the information that everyone received was the same. However this proved impossible to arrange because of conflicting schedules and availability of the nurses outside of their normal working hours. As a result the nurses were individually trained by the researcher, at times that were suitable to their working hours. The disadvantage of this situation is that the information taught would be similar, but not identical.

The nurses were given a training guide (Appendix L) which was broken into an instruction sheet for each month of the programme with a summary of the milestones for each month. The guide contained the activities or postures, examples of when these could be used, key points of facilitation to ensure the correct movement and

ideas to up- or down-grade the activity in case the infant was already coping easily with it or was not yet ready for the task in any given month.

The nurses were also taught basic principles for the programme as a whole, to convey the message to the mothers that they should have fun with their infants and watch their infants' reactions to the tasks rather than be dogmatic about the inclusion of all positions and fixated on milestone achievement.

The nurses had access to the researcher by telephone and regular contact and were free to ask questions regarding the programme throughout the duration of the research.

3.8 Outcome Measures

3.8.1 *Screening Questionnaire*

A screening questionnaire, developed by the researcher, was used to determine whether the infants were appropriate for the study. (Appendix K)

The screening questionnaire looked at the gestational age at birth, birth weight, length and Apgar scores, where the baby was born and any signs of difficulty at birth (prolonged foetal distress, birth apnoea, 'blue baby', need for oxygen, floppiness, stiffness, need for incubation etc.). The mothers were asked if they attended, or were intending to attend a mother/baby stimulation group.

The questions regarding the birth history were included to determine whether the baby suited the inclusion criteria for the study. Infants who were ill at birth, premature or who were born by emergency caesarean (suggesting foetal distress or a risk for birth hypoxia) would be excluded.

The questionnaire was also designed to draw out information regarding how the baby was positioned to sleep, who first told the mother how to position the baby for sleep and who the primary caregivers were.

The questionnaire was piloted using a group of 5 mothers, not participating in the study, attending a Mothers and Babies group. Adjustments to the questionnaire were made based on any ambiguity that they reported, or if the question elicited information from the mothers that was not anticipated or relevant.

3.8.2 *Baby's Day Diary©*

The use of diaries to research baby development has a long history[91] and allows parents to tell the narrative of their infant's activities reliably. It is preferable over retrospective memory of the day or events.[16]

The Baby's Day Diary©[114-116] was used with permission of Dr R Barr (Appendix M). The diary makes use of 'time rulers' in 5 minute intervals, which are shaded according to a key chart, depending on the infant's behaviour during that time. Arrows recorded above the ruler allow the person completing the diary to indicate the position in which the baby went to sleep. The diary has been created in order to provide parents with an easy means of recording the activities of their infants as they happen, or soon thereafter.

The diary was shown as a reliable means of recording infant crying in research,[114] using parental records via the diary and external recordings using audiotapes. The results showed a high correlation between what the parents recorded and what could be objectively measured on tape. The authors noted that the diary is limited when parents are not well motivated and is best used when the parents record events on a regular basis throughout the time period. The

diary has since been used to measure other infant behaviours such as crying related to carrying and crying related to feeding and infant position.[16]

The Baby's Day Diary© was adapted to meet the objectives of this study (Appendix N and O, each day 1 out of 3 days). Barr's research assistant changed the coding, from a key chart relevant to infant crying to the pertinent information regarding infant position. A separate diary was created for the usual care and intervention groups, as the instructions for the intervention group also included a request to mark off activity participation.

The Baby's Day Diary©, as it is designed for this study, therefore elicits information regarding the infant's behaviour and the infant's position over a 24 hour period. It records information as to whether the baby was asleep, awake or feeding (with a code if parent could not remember) and when awake, whether the baby was held or carried, sitting with support, sitting without support, lying on their back/side or lying on their front. Information was also obtained regarding the position in which the infant went to sleep in by the use of an arrow above the ruler. The parents in the intervention group were also asked to place an 'X' above the ruler each time they incorporated an activity or posture that was on the photo-sheet.

All parents were taught how to use the diary by the researcher at the time of the baseline assessment. There is a standardised format for this training and an instruction sheet that is provided by the original author (Appendix P).

3.8.3 *Peabody Developmental Motor Scales – 2nd Edition (PDMS-2)*

The PDMS-2 is a standardised assessment tool which provides normative data for developmental categories. It is a widely used, therapist driven, assessment tool which assesses gross and fine

motor development in infants from birth to 7 years of age. The PDMS-2 comprises 3 subscales, yielding age standardised normative quotients for Gross Motor Quotient (GMQ), Fine Motor Quotient (FMQ) and a Total Motor Quotient (TMQ). It can be used to determine which fine and gross motor skills a child has mastered, and which are immature for their age.[109, 117] The items on the test have a three point scoring system, resulting in a score of 0, 1 or 2 depending on a description of the quality of the movement, as defined by the authors, in the testing booklet. The test procedure creates a basal and ceiling effect which gives the total score. This raw score is then converted to a standard score using age stratified, normative tables. The standard score is recorded on a Profile/Summary sheet. Quotient scores are created for GMQ and FMQ using the sum of the raw scores related either to a gross or a fine motor skill. The TMQ is the sum of all the raw scores, converted to a quotient by means of a table (Table B1 of the manual.[109])

The assessment is rated highly for reliability and validity and is widely used to assess infants for developmental delay,[16, 118] because it allows for a qualitative evaluation of emerging skills rather than a 'yes/no' checklist of skill competence. Inter-rater reliability (r = 0.96 for the overall test) and test-retest reliability (r = 0.89 for the overall test) are high.[119] Content validity is assured with an internal consistency α = 0.97.[109, 119] The test can be used as a measure of change over time in a pre- and post-intervention evaluation.[119]

3.9 Method of Data Collection

3.9.1 *Sample selection and Screening questionnaire data*

Nursing sisters approached all mothers of eight week old infants who attended their clinic for vaccination and weighing. An information sheet and consent form with biographical screening questionnaire

was given to each mother to inform them about the study and to explain the process (Appendix H and I).

The mothers read the information sheet while they were waiting for their appointment, and those who agreed to participate, were asked to complete the consent form and biographical questionnaire at that time and to leave them with the nursing sister (Appendix K).

Biographical questionnaires and consent forms were collected from the Well-baby clinics, by the researcher, in sealed envelopes, so that the names of the parents would not be directly associated with the clinic from which they were gathered. These were collated and checked by a research assistant to ensure that they met the requirements for the study. Mother's names and contact details were placed on a single list in no particular order. Appointments, to complete the baseline assessment, were made as soon as the researcher was given the names of the mothers. The researcher was therefore blinded as to which group the parents came from and mothers were asked not to reveal which clinic referred them for the study.

3.9.2 *Assessment of infants*

At the time of the baseline assessment, infants were assessed with the PDMS-2. Raw scores were recorded at the time of the assessment, then converted to standard scores and plotted on a Summary/Profile form. Some of the assessments were done as a home visit and some were scheduled to take place at the therapy rooms of the researcher, depending on the preference of the mother. The assessment requires a table and minimal floor space to complete. A consistent set of toys (rattles, cloth, ball, soft toy, pull toy and paper) were used with the infants, but if the child was not responding to these, their own toys were also employed to elicit the responses

required by the PDMS-2. The infants were assessed as soon after being recruited into the study as possible.

At the appointment for the baseline assessment, all parents were taught how to complete the diary pages by the researcher, using the standardised format supplied by Barr (Appendix P). As there was a difference between the diary pages for the two groups, the first set of diary pages to be given to the parents by the researcher, was contained in sealed envelopes, prepared by the research assistant, so that blinding was ensured for the researcher. Subsequent pages were left with the nursing sisters and the parents received a new set with each monthly visit. For those parents enrolled in the intervention group, this coincided with the teaching of the new activities and the receipt of the monthly photo sheets.

All diary pages were collected by the researcher for logistical purposes, after having them placed in sealed, unmarked brown envelopes by the nursing sisters. A collection run of all the clinics was done on a single day, on a monthly basis, so that no one clinic would stand out (as it might if collection was individual). The envelopes were returned to the research assistant who replaced the name of the baby with a code so that diary pages could be analysed without affecting the blinding of the researcher.

Reassessments were scheduled to take place at 28 weeks. Developmental data after this time would have been affected by infant choice, as infants begin to make their own choices, regarding sleeping position, between five and six months.[61]

All the infants were reassessed using the PDMS-2 and the follow-up scores were plotted on the Summary/Profile Form. Appointments were made by the researcher as soon after the infants were 28 weeks as possible. In the case of some of the babies, recruited late in the enrolment process, the reassessment fell over Christmas and so

appointments were made as early in January as possible. These infants were scored for an older age on the PDMS-2.

3.10 Data processing methods and Data analysis

3.10.1 *Organisation of Data*

Data from the biographical questionnaire, PDMS-2 Examiners Record Booklet and Profile/Summary Form and Baby's Day Diary® were coded into numerical values using several Excel spread sheets.

These were organised as:

- Demographic information: age, gestational age, weight and length, position in the family and number of siblings of each individual infant, and were arranged by group (intervention or usual care)
- Raw scores for the baseline assessment and follow-up assessment were recorded and arranged by group.
- Quotients (FMQ, GMQ, TMQ) for both assessments were generated by calculating the sum of the scores and converting to a quotient. These were also arranged by group.
- Diary data, listed by individual, with a sum of the minutes in each category per day of the set. For the sets of 3 days, an average time was calculated to allow for variations in daily occurrences and non-typical days. Thereafter, a summary page was created that clustered Diary sets together by age and group (i.e. diary set 1 for the usual care group versus Diary set 1 for the intervention group)

Diary data was then converted to averages of each set and represented as comparative graphs. The diary set with no comparative data was represented as a pie chart.

3.10.2 *Statistical Methods*

Descriptive statistics were used to describe, summarise and organise the results obtained from the assessments.

The raw scores and quotients were used to generate means, ranges and standard deviations for the various variables using an Excel spread sheet. This data was used in further analysis.

Groups were compared at baseline using Student's two-sample t-test to assess randomization and these results were also confirmed using Wilcoxon's rank-sum test because of the small sample sizes. The change from baseline to follow-up was also assessed between groups using Student's two-sample t-test, however, an analysis of covariance (ANCOVA) with baseline value as covariate was also done. Furthermore, in a rather exploratory way, within group change was assessed with Student's paired t-test. Testing was done at the 0.05 level of significance.

Statistical analysis was conducted from the means using the "Strata" computer programme.

CHAPTER 4 RESULTS

This chapter describes the results observed when comparing the dyads who participated in the IPCP and those who did not. The demographic results are illustrated by means of tables, as are the baseline and follow-up assessment results. Data from the Baby's Day Diary© pages are represented as activity profile pie charts.

4.1 Population Sample

A total of 37 mother-infant dyads agreed to participate in the study. Two infants (one from the experimental and one from the control group) were excluded before the baseline assessment was conducted as they had been born prematurely (<37 weeks gestational age). Thirty-five (35) infants were assessed at the baseline (mean 9.7 weeks, range 8 – 13 weeks).

Five mother/infants dyads (14%) were lost to follow-up with the following reasons provided:

- Time constraints (3),
- Illness of an older sibling (1)
- An accident involving a parent around the time of reassessment (1).

The losses were from the control group, with no mother-infant dyads dropping out of the study's experimental group.

4.2 Sample Demographics

Table 4.1 represents the demographic data of the infants by group at the time of the baseline assessment and age at reassessment. Non-significance between the groups are represented as 'ns' rather than reporting numerical values.

Table 4.1: Demographic Data for the Intervention & Usual care Groups

Infant demographics	Intervention Group (n = 13) mean	(sd)	Usual Care Group (n = 17) mean	(sd)	p-value
Gestational age at birth (weeks)	38.84	(1.2)	38.58	(0.80)	ns
Weight at birth (kg)	3.19 kg	(0.35)	3.15 kg	(0.45)	ns
Length at birth (cm)	49.5 cm	(2.1)	49.2 cm	(2.05)	ns
Age at baseline assessment (weeks)	9.79	(1.65)	9.69	(1.31)	ns
Age at reassessment (weeks)	29.75	(2.7)	29.18	(1.27)	ns

No significant difference was observed between the two groups at the time of the baseline assessment in their gestational ages, birth weight or length. Neither was there a significant difference in the ages of the groups at baseline assessment or reassessment. (Table 4.1) No distinction was made between gender groups, as the differences between males and females in terms of motor development are considered "trivial".[43]

All participants in the study were white. The use of a single race group of candidates was not intentional, but did serve to reduce any potential confounding factors that culturally directed child rearing practices may have on motor development.[16]

Data regarding sleeping positions and care of the infant was gathered using the questionnaire at the time of the baseline assessment. Further data regarding caregivers of the infant at reassessment (follow-up) was based on verbal information and recorded on the same data sheet for each infant. The data from these background questions is summarised in *Table 4.2*.

Table 4.2: Positioning and parenting data regarding sleep behaviour and primary caregiver for Intervention and Usual care Groups

	Intervention Group (n = 13)	Usual care Group (n = 17)	p-value[1]
Percentage of mothers for whom the enrolled infant is their first child	83%	80%	ns
Percentage of infants who slept exclusively on their backs	37%	7%	ns
Percentage of infants who slept exclusively on their sides	42%	71%	ns
Percentage of infants who slept in a combination of back and side-lying positions	21%	22%	ns
Percentage of infants who were kept in their preferred position in foam wedges	50%	64%	ns
Percentage of infants who were positioned in prone for day time naps	8% (n = 1)	0%	ns
Percentage of infants cared for by mother at baseline	100%	100%	ns
Percentage of infants cared for by mother at follow-up	8% (n = 1)	6% (n =1)	ns

[1] Fishers exact test

The above data sets forth care practices of the mothers, which are pertinent to this study. No significant differences were found between the groups relating to the positions in which mothers chose to put their infants to sleep.

Infants were consistently cared for by their mothers in early infancy and were almost universally placed in day care or with a day-mother by the time they were reassessed at 29 weeks.

It is worth highlighting the information presented that indicates the successful randomisation of the two groups at baseline, despite the need to practise cluster randomisation in the study design. Tables 4.1 and 4.2 provide the demographic information of the infants at baseline provide and show that there is no significant difference between the groups in their demographics, initial ages or age at cessation of the study. There is also no significant difference found in the care-givers' practices regarding positioning for sleep, or in the number of infants in each group who were placed with a crèche or alternate caregiver as the study progressed. In both groups the majority of the children were their parents' first child, implying that they did not have to share their parents' attention or time resources with other siblings.

4.3 Assessment results

The motor development of the infants and the possible effect of the IPCP can be compared in two ways:

- by comparing the scores on the PDMS-2 *between* the two groups and also
- by comparing the standard scores *within* both groups, from the time of the baseline to the time of the follow-up assessments.

Table 4.3: Comparison of mean values for the PDMS-2 at Baseline and Follow-up assessment results by group and within groups

Parameter		Intervention Group (n = 13) mean (sd) range	Usual care Group (n = 17) mean (sd) range	Two-sample t-test p-value[1]	ANCOVA with baseline as covariant p-value
		Within group changes	Within group changes	Between group changes	
Reflexes	Baseline	9.08 (0.95) 8 – 10	9.06 (0.90) 8 – 10	0.95	
	Follow-up	10.08 (1.38) 8 – 11	9.29 (0.85) 8 – 10	-	
	p-value[2]	0.01	0.361	-	
	change	1.00 (1.22)	0.23 (1.03)	0.07	0.05
Stationary	Baseline	9.23 (1.09) 7 – 11	8.88 (0.70) 8 – 10	0.29	
	Follow-up	11.61 (1.98) 8 – 16	10.53 (1.74) 6 – 12	-	
	p-value[2]	0.00	0.00	-	
	Change	2.38 (1.60)	1.64 (1.86)	0.26	0.21
Locomotion	Baseline	9.46 (1.13) 8 – 11	9.65 (0.79) 8 – 10	0.59	
	Follow-up	9.54 (1.40) 7 – 12	8.47 (0.87) 7 – 10	-	
	p-value[2]	0.85	0.00	-	
	Change	0.77 (1.44)	-1.17 (1.42)	0.02	0.01
Grasping	Baseline	9.23 (0.60) 8 – 10	9.24 (0.56) 9 – 10	0.98	
	Follow-up	11.00 (1.30) 9 – 12	9.94 (0.97) 9 – 12	-	
	p-value[2]	0.00	0.03	-	
	Change	1.77 (1.53)	0.71 (1.26)	0.04	0.01
Visual Motor Integration	Baseline	10.23 (0.44) 10 - 11	10.17 (0.53) 9 – 11	0.76	
	Follow-up	10.46 (0.88) 9 - 12	9.94 (0.43) 9 - 11	-	
	p-value[2]	0.27	0.21	-	
	Change	0.23 (0.73)	-0.24 (0.75)	0.09	0.04

[1] *These results were confirmed with Wilcoxon's rank sum test*
[2] *p-value for Student's paired t-test within groups*

Table 4.3 is a summary of the standard scores (mean, standard deviation and range) obtained for each group of infants at baseline

assessment and again at follow-up assessment. The differences between the two groups at baseline, indicating the p-values for the baseline assessment, is also reflected. Further analysis between the groups is given by ANCOVA with the baseline as the covariant.

Table 4.4 Comparison of mean values for the PDMS-2 at Baseline and Follow-up assessment results by group and within groups

Parameter		Intervention Group (n = 13) Mean (sd) range	Usual Care Group (n = 17) Mean (sd) range	Two-sample t-test p-value[1]	ANCOVA with baseline as covariant p-value
		Within group changes	Within group changes	Between group changes	
Fine Motor Quotient	Baseline	95.46 (5.10) 85 – 104	94.94 (3.13) 89 – 98	0.73	
	Follow-up	103.23 (8.65) 85 – 119	96.23 (5.74) 81 – 104	-	
	p-value[2]	0.00	0.47	-	
	Change	7.77 (6.13)	1.18 (6.64)	0.01	0.00
Gross Motor Quotient	Baseline	98.15 (2.88) 94 - 103	98.24 (2.14) 94 – 100	0.93	
	Follow-up	104 (6.89) 97 - 112	99.82 (4.36) 97 - 106	-	
	p-value[2]	0.00	0.21	-	
	Change	5.85 (6.62)	1.59 (5.08)	0.05	0.05
Total Motor Quotient	Baseline	95.92 (4.17) 94 - 101	95.53 (2.53) 94 - 98	0.75	
	Follow-up	103.61 (7.76) 89 - 116	97.18 (4.84) 86 – 104	-	
	p-value[2]	0.00	0.22	-	
	Change	7.70 (6.42)	1.65 (5.41)	0.00	0.00

[1] *These results were confirmed with Wilcoxon's rank sum test*
[2] *p-value for Student's paired t-test within groups*

Table 4.4 is a summary of the quotient scores (mean, standard deviation and range) obtained for each group of infants at baseline assessment and again at follow-up assessment. The differences between the two groups at baseline, indicating the p-values for the

baseline assessment, are also reflected. Further analysis between the groups is given by ANCOVA with the baseline as the covariant.

Further conclusions regarding randomisation at the baseline can be drawn from Table 4.3 and Table 4.4. For each of the baseline standard scores, across the five subtests, a mean and p-value has been reported and none of the baseline subtests, nor the baseline quotient scores, show a significant difference between the intervention and usual care groups, thus they were comparable at baseline. This speaks to the homogeneity of the two groups and indicates that, at baseline, the infants were developing normally.

It can also be noted, from the ranges reported for the baseline scores, that only one infant would have been of clinical concern, that is in the 'below average' range, at that initial assessment. This infant, from the intervention group, received below average scores for stationary positions (range 7 – 11), and FMQ (range 85 – 104). (Appendix Q, specifically Figure Q2 and Q6) No infants in the usual care group obtained scores in the 'below average' range, and were therefore not a concern, from a therapeutic point of view.

Further, the locomotion and visual motor integration scores tested lower at reassessment for the usual care group (change at -1.17 and -0.24 respectively), both of which are significant on ANCOVA with baseline as covariant.

4.3.1 *Comparison of results within the groups*

In an explorative manner, the significance of the change within groups was investigated from the time of the baseline assessment, following the trajectory of normal development. As normative data for the PDMS-2 is provided for age progression, a normal pattern of scores can be anticipated for a healthy sample of infants.

Table 4.3 and Table 4.4 show that the usual care group did not display a significant difference in most of the subtests, nor in the quotient scores to the anticipated developmental trajectory. The subtests showing a significant difference were the stationary scores (p = 0.00), locomotion (p = 0.00) and grasping (p = 0.03)

The results observed within the intervention groups show a significant difference in reflexes (p = 0.01), stationary (p = 0.00) and grasping scores (p = 0.00) scores. More importantly, significant changes are observed in all the quotient scores (Table 4.4).

4.3.2 *Comparison of participants between groups*

4.3.2.1 Mean values and two sample Student t-test

Table 4.3, indicates that the mean values of the assessment scores at the second assessment are consistently higher for the intervention group than the usual care group. When the assessment results were analysed with the Students two-sample t-test, significant differences could be seen between intervention and usual care groups in the following areas: locomotion (p = 0.02), and grasping (p = 0.04), and likewise, from Table 4.4 the FMQ (p = 0.01) and the TMQ (p = 0.00).

4.3.2.2 ANCOVA results

When results between the groups are analysed with an analysis of covariance (ANCOVA) for change from baseline between the groups, with the baseline as covariant, significance is enlarged to include the visual motor integration score (p = 0.04), with the reflex and stationary scores and the GMQ remaining insignificant.

4.3.2.3 Quotient Results

In the final analysis, the most reliable and significant scores of the PDMS-2 are the quotient scores.[109] While the subtest scores can provide a glimpse at what is happening in different spheres of development, the designers of the PDMS-2 consider the quotient scores to be the final point of discussion.

In the comparison between the intervention and usual care group, it can be seen from Table 4.4, that the FMQ and TMQ scores show significant difference, with the GMQ being insignificant. This shows the effect of the programme to the positive in infants in the intervention group.

The effect size that the developmental programme achieved was an improvement of 7.77 (FMQ), 5.85 (GMQ) and 7.70 (TMQ) points.

4.4 Analysis of diary pages

Diary sheets were received from nine of the mothers in the study. Four sets of sheets were from mothers in the intervention group and five sets from mothers in the usual care group. One set of diary pages was excluded from the data set as the mother had provided three days over three months, instead of the requested three days per month for three months. As a result this set of sheets could not provide an average to allow for typical or non-typical days and was therefore rejected.

Diary sets representing the following days were obtained:

Table 4.5: Annotation of the complete sets of diary pages returned for the Intervention and Usual care groups

Diary set	Intervention group	Usual care group
1 (9 – 12 weeks)	4	4
2 (13 – 16 weeks)	1	2
3 (17 – 20 weeks)	1	1
4 (21 – 24 weeks)	1	0
5 (25 – 28 weeks)	1	0

Due to the paucity of data, representations of each set are given as Activity Profiles (AP) by group and similar ages are grouped together.

Throughout the activity profiles, the sleeping and feeding posture is considered as constant, due to the mother's responses regarding

their infants sleeping positions (see table 4.2) and assumptions regarding standard feeding positions (side-lying or supine or variations thereof).

As a result, the area of interest encompasses the time spent awake and more specifically, the position of the baby when awake. These positions are given as broad categories on the parenting diary (Appendix N and O). Of particular interest in this study is the time spent in prone.

4.4.1 *Diary set 1 (9 – 12 weeks)*

Figures 4.1 shows the mean times calculated for the activity profiles for Diary set 1, by group. The mean time spent with the infants lying prone is similar (1% of total time) and the difference is not significant. The mean score falls below the recommended 30 minutes for infants to be positioned in prone throughout the day.

The usual care group reflected a range of 0 – 30 minutes in prone and the intervention group had a similar range of 0 – 35 minutes.

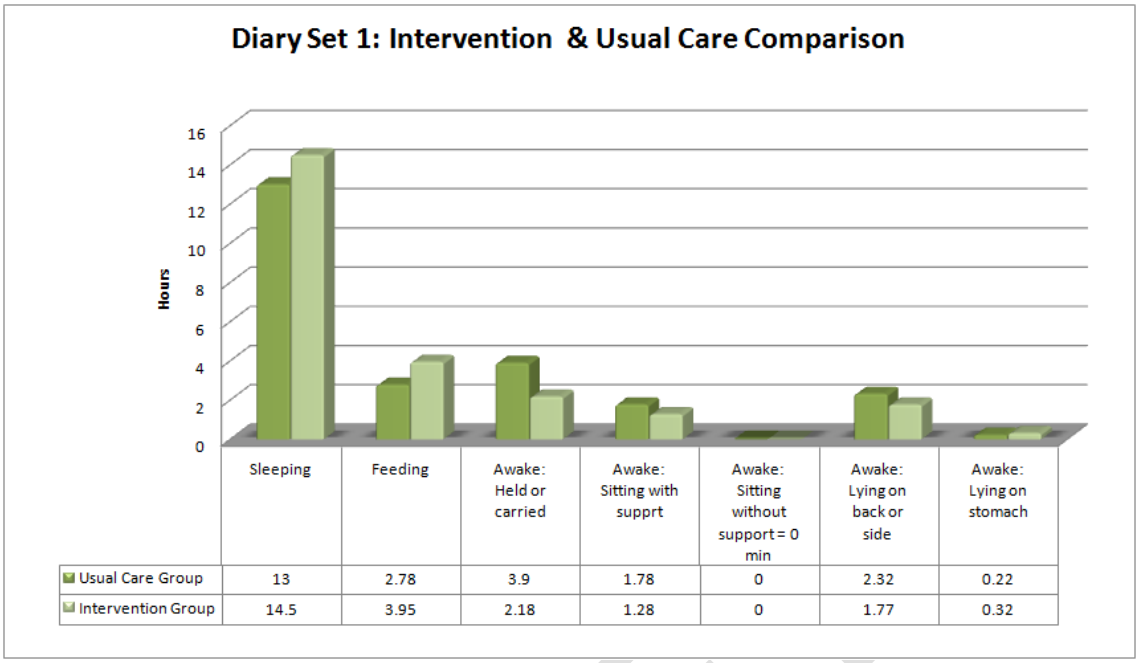

Figure 4.1 Comparative graph for the diary set 1 (9 – 12 weeks) for infants in the usual care and intervention groups, expressed in hours.

4.4.2 *Diary set 2 and 3 (13 – 20 weeks)*

As shown in figure 4.2 which represents the activity profiles for Diary Set 2 and 3, for both groups, the time spent with the infants lying prone is similar to Diary Set 1 (2% of total time).

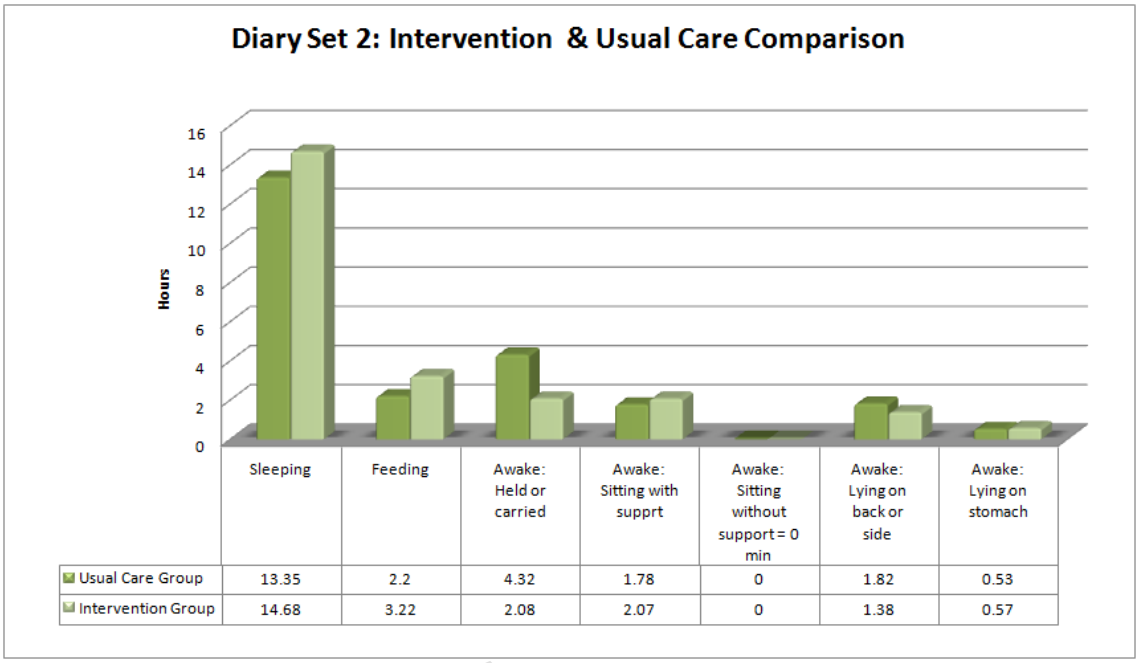

Figure 4.2 Comparative graph for diary sets 2 and 3 (13 - 20 weeks) for the usual care and intervention groups, with times expressed in hours.

Between the two groups there is parity regarding the amount of time spent in prone. The ranges for the two groups were:

- Usual care group 0 – 105 minutes,
- Intervention group 15 – 55 minutes.

4.4.3 *Diary set 4 and 5 (21 weeks – reassessment at 28 weeks)*

No diary pages were provided by mothers in the usual care group for the months immediately preceding the reassessment, so a comparison is not possible.

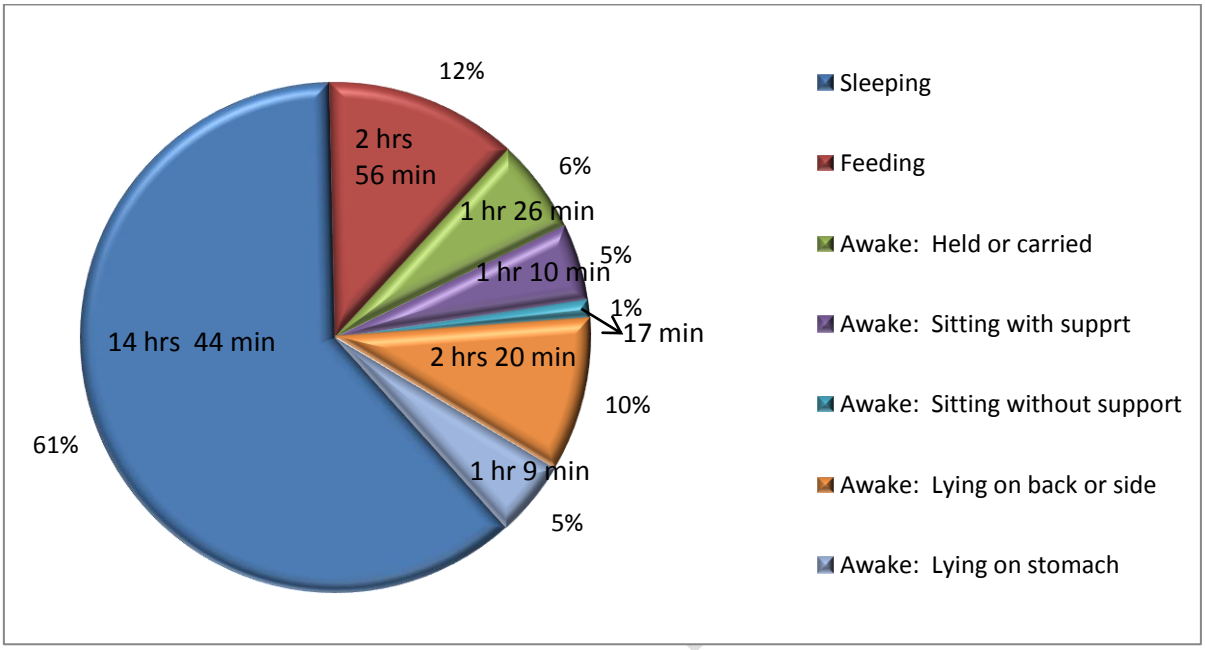

Figure 4.3 Activity profile for diary set 4 and 5 (21 - 28 weeks) for the intervention group.

The diary pages provided by the mothers in the intervention group for this activity profile were well detailed and considered. The mothers managed to include between 2 and 4 activities from the programme into each day's tasks.

The range of minutes spent in prone for the two infants who represented this AP was from 60 – 95 minutes.

It is interesting to note that the only infants who were sitting independently at the time of reassessment were from the intervention group.

4.5 Null hypothesis

The null hypothesis formulated in Chapter 1 stated that: There will be no difference after six months, in the motor development of supine sleeping infants, whose parents incorporated activities embedded into their normal ADL to challenge their infants' postural muscles and those infants whose parents did not.

As a statistically significant difference between the TMQ of the intervention and usual care groups has been found at reassessment ($p = 0.00$), the null hypothesis is rejected.

4.6 Summary of results

An analysis of the scores obtained at the baseline assessment showed no significant difference, indicating that the groups were homogenous. Only one infant fell in the 'below average' range, and this infant was from the intervention group. This indicates that both groups were developing normally for their age at baseline.

An analysis of scores within each group revealed that there were some significantly different scores at the time of reassessment. In the intervention group, significant changes were reflected in subtest scores (reflex, stationary and grasping scores) and in all the quotient results. (Table 4.3 and Table 4.4)

Within the usual care group a significant difference can be noted for the stationary and grasping subtest, suggesting that these areas are improving without intervention at this age. A significant difference is observable for locomotion, but change was in the negative direction. (Table 4.3) No statistically significant difference could be found for any of the quotient results. (Table 4.4)

Evidence of differences between the groups is also seen at reassessment, at a subtest and quotient level. Significant differences are seen in the locomotion, grasping and visual motor integration subtests. More importantly, significant differences are obtained between the two groups on the Fine Motor and Total Motor Quotient results. The null hypothesis, stating that there will be no difference between the two groups post-intervention, is therefore rejected.

Unfortunately, due to the paucity of data from the diary pages, few conclusive findings could be made regarding the frequency of the insertion of activities into the ADL of mothers. The mean time that infants spent in prone, at 8 – 12 weeks, was less than the recommended 30 minutes, and there was no significant difference between the two groups at any age. No comparative data exists for the months immediately prior to reassessment. Infants in the intervention group, for whom diary data was returned, spent 60 – 95 minutes in prone each day. Their mothers managed to insert between 2 and 4 IPCP activities into their ADL.

CHAPTER 5 DISCUSSION

The discussion will consider the study in terms of the recruitment and demographics of the participants, the loss to follow up and the possible effect of a small sample group. The development of the programme and implementation thereof is considered with the results in relation to the objectives, which were:

- To design and pilot a postural control programme for infants, in which defined prone activities/postures were embedded into everyday activities of the mothers.
- To compare the motor development of supine sleeping infants after 6 months of age, whose parents incorporate activities embedded in the normal activities of daily living (ADL) that challenge the infants' postural muscles, with those whose parents do not.
- To evaluate the ease with which mothers incorporated postural control activities within their own ADL.

5.1 Demographics

The participants in the study included the nursing sisters recruited to provide the programme to mother-infant dyads. Private Well Baby Clinics were conveniently sampled and provided services to a homogenous population in terms of socio-economic status. Unintentionally, all infants were from a single race group, therefore

the findings cannot be generalised beyond the group assessed in this study.

The sample of mother-infant dyads recruited into this study was ultimately less than the 50 participating dyads that was suggested by the statistical calculation. This results in a decrease in the power of the study, which is likely to have dropped below 80%. This drop in sample size could result in a type II error being made when conclusions are drawn regarding efficacy of the programme. The two groups of infants recruited, however, were comparable as there was no difference at baseline in demographics or in their scores on the PDMS-2. This, combined with the randomisation of the clinics, and the blinding of the assessor who completed the baseline and follow-up assessments, adds strength to the study. Allocation could not be concealed from the participants because each nurse and the mothers had to know if they were in the intervention group or not.

A loss to follow-up in the study was higher than 10%, and the results for the infants were excluded from the data analysis. This presents a potential bias in the study, as those who dropped out could have differed from those continued. It may be that parents who had less time available left the study. Since the losses were only from the usual care group, it is also possibly due to consistent follow-up by the nurses at those clinics running the intervention groups, as they were very aware of who was involved and seemed more motivated to participate during the initial phase of the project. Nurses facilitating the usual care group were often not aware of who was in the study group. The loss of nurses affected the randomisation of the allocation of the clinics, which also imposes limitations on the results in relation to the population they could apply to.

The results in terms of the programme and the motor development of the infants were found to be positive for the sample in the study. Factors related to this are considered below.

5.2 Development of the IPCP

The Infant Postural Control Programme is rooted in the occupational science philosophy base, which considers the complex psychology in the understanding of occupations. This theory base holds that activities have deeper meanings that define us as individuals, and covertly influence the construction of complex daily routines which sustain motivation, even in unpleasant or labour-intensive tasks. This theory base is being validated in the growing literature which asserts that humans learn and change by *doing.*[53, 120] Findings, in the fields of neurophysiology and motor control theory, are showing that practice, and even therapy, outside the context of normal human activity is meaningless to people.[53] Neuroplastic change occurs in the context of self-directed, 'real life'.

Similarly, interventions that fall outside the flow of human occupation are also meaningless to people.[24] Without proper integration into daily life, treatment regimes and home programmes are abandoned for those tasks which are time urgent[24] and adaptations are made and sustained as far as possible, but below optimal.[23, 24] Even therapists aren't able to sustain the 'optimal' regimes outside of the context of normal routine construction.[76]

Mothering has been discussed in the context of a mother's role in routine construction. Mothers of young infants are faced with the need to insert activities, which require additional time in their daily routine, in order to stimulate their infant's development, and simultaneously meet their own needs within the mother-infant dyad. Mothers, are skilled at inserting such activities into their days,[24] and

are in many cases, content to put their own pressures aside for the benefit of their infant.[34] To sustain this unfolding, however, is difficult because of the overwhelming, all encompassing nature of mothering.[29] So when an infant shows distress, or the value of the learning time appears to dim in the face of other demands,[21] a natural reaction is for the mother to stop providing the time, or do the task herself, and in the long run, the opportunity to practice a skill is afforded the infant less and less.[21]

This seems to be the case in the development of postural control, through the minimal use of the prone position in infancy. Infants who sleep in supine are inclined to protest when placed in prone when awake.[8] They are less practiced in the position and do not have the endurance to hold their heads against gravity. Since the benefit of putting the infant in prone when awake is not initially obvious to a parent, and will only become relevant several months after birth, mothers reduce the amount of awake prone time in the construction of their routine.[8] Instead, they make use of various positioning devices to enable their child to see them as they move through time and space in a manner that is intrinsically dyadic.[26, 28, 65, 98] In this upright position, infants are less mobile, but readily develop hand skills and are more likely to be appeased. As a result, no effort to challenge the postural muscles is applied, because there is no stressor to do so.[51]

The need for prone awake time is substantiated by the finding that children who do not develop good postural control are at risk for failure to develop more complex motor skills and motor co-ordination, even if the deficits are subtle.[51] This, in turn could result in social, emotional, learning and activity level problems.[54] To miss out on prone postural development, is therefore not to be considered lightly.[27, 52] Early prevention programmes are justified, in the face of

a generation of children who are increasingly inactive, obese and at risk for diabetes and other sedentary lifestyle related illnesses.[84, 121]

It was in the light of the above that the Infant Postural Control Programme was developed. All of the activities chosen were selected for the challenge they provide for the postural muscles, such as the endurance needed for lifting the head against gravity, weight bearing through the shoulders, developmentally appropriate rotation for oblique abdominal muscles and variations in flexion and extension to balance the development of back and abdominal muscles. The positions used require increasing amounts of stabilisation from the core muscles, and challenge head and neck control at varying levels over the months.[47]

More importantly, however, the programme was designed to fit seamlessly into the household, childcare, leisure and self-management tasks that a mother needs to do in a day. Anticipated benefits included enhanced parenting knowledge and self-efficacy in promoting postural development. By providing the photo-sheets as a memory aid, mothers could be empowered to make use of the postures as often and as creatively as possible, inserting postures and challenges into any number of ADL scenarios. The photo-sheets were also designed with an element of aesthetic design; the desire for the programme to appear fun and simple and therefore manageable.

Due to this approach, as opposed to a 'one size fits all' programme, it is unclear precisely what mothers did on a daily basis with the programme. Each mother would have used it as she perceived best, tailoring it to her particular baby and circumstance.

An effort to capture a snapshot of these days was made by using the Baby's Day Diary as an outcome measure. But few mothers were able to complete these diary pages for the purposes of this study,

and ironically, the universal reason given was, that they did not have time. The diary pages themselves fell outside the flow of a daily routine, did not hold intrinsic value for the mothers, and, as such, were not afforded the necessary time to complete them.

5.3 Implementation of the IPCP

The initial intent in the study design was to teach all of the nurses who were assigned to the intervention group the programme at a single session, thereby ensuring that the training that they received was the same. Unfortunately this proved impossible to arrange due to varying schedules and work times. As a result, the training that the nurses received would have been similar, but not identical. There was also limited time to practice the techniques taught and there could be no checks (such as a test) in place to determine the manner in which the nurses conveyed the information.

Because it was not possible to observe each Well Baby visit to determine what was taught by the nurses to the mothers, there was no way of controlling the fidelity of the intervention. As a result it is difficult to gauge whether the 'dosage' and frequency of the intervention was carried out as intended.[45, 122] One strategy to ensure that the nurses taught the same programme, was the use of a training manual for the nurses which gave background information to the photo-sheets and would hopefully provide some uniformity.[8, 122] The photo-sheets were also used in an attempt to reduce the 'broken telephone' factor. Further, it was hoped that they would improve the consistency with which the mothers understood the handling techniques as the photographs from which they were learning were the same. It was hoped that the photo sheets would improve the consistency of the time spent with the nurses as the sheets could provide structure in teaching the programme.

The amount of time the nurses spent with the mothers was another factor which was difficult to control for. Theoretically, nurses from both groups should spend an equal amount of time talking to the mothers about development at each visit. The variation would theoretically be in the content of these discussions. This would provide an attention-placebo effect to the usual care group.

However, in actuality it was noted that some practices spent very little time talking about stimulation and focused rather on nutrition and growth. Also, some practices had appointment times for the mothers and others operated on a walk-in basis. The latter was inclined to have shorter appointments with less opportunity for asking questions. Therefore, mothers who fell within the intervention group were assured of more time with the nurse as a definitive amount of teaching had to be accomplished in order for the mother to do the programme in the next month.

A further step which would have bolstered the understanding of the ease with which mothers implemented the programme would have been to run focus groups with the mothers at the end of the data collection or to have made use of a questionnaire to determine whether they understood the programme. An alternate approach in which to determine the success of the programme is whether the mothers perceived it to be successful, rather than whether there was developmental change.[78] This bears investigating in future research.

5.4 The effectiveness of the IPCP

The effect of the programme was inferred by the developmental progress of the infants. The results indicate that there is an improvement in developmental trajectory between the usual care group and the intervention group that is significant in the areas of reflex integration, locomotion, grasping, visual motor integration,

Fine Motor Quotient and Total Motor Quotient. No significant differences were found in the stationary sub-test or the Gross Motor Quotient.

These scores are significant from a clinical point of view. That the locomotion score is significantly improved in the intervention group is a promising finding as it implies that the programme has improved the muscular basis for movement, as well as keeping the infants on par with the age norms for movement. This suggests that both the quality of the movement, as well as the mastery of the milestone, are as desired.

That the grasping score is significantly different implies that the muscular basis for reaching and grasping (i.e. the shoulder girdle and trunk co-contraction) is also improved from a qualitative point of view.

Likewise, the higher scores in the FMQ and TMQ suggest that the fine motor abilities are based on a strong underlying muscular base of movement (working on the principle of distal function from proximal stability).[51]

These scores suggest a deeper level of integration that is being acted upon by the programme. That the reflex scores have improved in the intervention group implies that those infants are better able to integrate and adapt reflex patterns in a more mature manner. The process of overriding the reflex patterns is theorised to be an important goal of early motor development.[47]

Furthermore, the differences between the groups in the visual motor integration score also suggest a more mature integration of visual perception, cognitive processes and motor adaptation for the infants in the intervention group. Visual motor integration is affected by visuo-spatial development, and distance sense is inherent to this and

is developed in infancy.[49] These visual perception skills, which underlie visual motor integration, can be challenged and enriched by making use of different body positions while engaging in perceptual tasks.[49] It is possible that the intervention group demonstrated a normal trajectory in the development of visual motor integration because of the varied positions used, and the usual care group tested significantly lower due to a lack in the variation of positions and reduced visual-spatial experience.

One possible explanation for the parity in stationary scores between the two groups, is that many of the criteria of the PDMS-2 at 6-months are dependent on the ability to sit, with very little movement away from the base of support being required. Given the wide use of seating devices in our society today, it is likely that sitting is a skill that is practiced often by both groups of infants. What is of developmental importance is the ability to move away from the base of support to reach for an object, or shift to the side or downwards into prone. A balance between stationary strength and mobility is the key in developmental paths. The pattern of stationary and locomotion results suggest that the infants in the intervention group have developed both mobility and stability by this age, whereas the infants in the usual care group appear to have a limited repertoire of movements away from static sitting.

Furthermore, the trend of mobility and stability in the intervention group seems to have a cascading effect to grasping and fine motor skills, in the manner that theorists suggest is beneficial – that proximal stability at the shoulder enhances distal function of the hands. Although there doesn't appear to be a causal relationship in development of fine motor skills from early hand skills,[51] proximal strength allows for greater degrees of freedom in the arm and hand and thus improved dexterity of grasps and hand use.[47]

Conversely, in the usual care group, the locomotion sub-score saw a statistically significant regression, while grasping scores showed a statistically significant improvement. This seems to echo the findings presented by Viholainen et al (2006) in their study of relationships between motor domains.[51] Both this study and the Viholainen study suggest that infants who are not as mobile are inclined to develop early hand skills. As opposed to the study by Viholainen et al (2006), this study is not sufficiently longitudinal to determine the consequences to fine motor skill acquisition. The study, conducted by Viholainen et al (2006), went on the determine a negative correlation between early hand skill development and gross motor skill attainment.[51]

The results presented for within group change in the intervention group indicate an improvement in the Gross, Fine and Total Motor Quotients, which suggests that the IPCP achieved the objectives set within this sample, that is, of improving postural control of infants by embedding appropriate activities within the ADL of the mother. It appears that mothers were able to implement the programme sufficiently to effect a change in the trajectory of their infant's development. The infant who was delayed at baseline was not found to be delayed in motor development at reassessment, which is clinically gratifying.

It should, however, be noted that this South African sample of usual care infants were not found to be delayed to the extent that is suggested in the international literature,[16] or in recent studies conducted in this country.[66]

An explorative exercise was conducted to compare the findings of Majnemer and Barr (2006) with the reassessment results from the usual care sample of South African infants to determine whether the extent of motor delay was comparable between the two groups.

The results from this South African sample, at the time of the baseline assessment, showed that two infants in the intervention group, recorded TMQ scores of 89, thus falling in the "below average" range (80 - 89).[109] For each of these infants, a low FMQ was the reason for the low TMQ. At 28 weeks, the reassessment results yielded improved results for both of these infants. One had a residual, below average FMQ, but a normal TMQ. The other had no persistent problems.

At the time of the baseline assessment, all infants in the usual care group fell within the average range. At 28 weeks, the reassessment results for the usual care group showed that one infant had a below average TMQ, while another had a below average GMQ, with a normal TMQ.

From the point of view of clinical importance, the above mentioned three infants who had below average results at re-assessment, would warrant further follow-up or intervention, as a result of having a low FMQ, GMQ or TMQ. This represents 10% of the total sample.

However, for the purposes of the comparison with the sample recruited by Majnemer and Barr (2006), only infants in the control group who required follow-up will be considered (n = 2), which represents 6% of the total sample, or 12% of the usual care group.

In comparison, the study by Majnemer and Barr (2006) makes use of a lower clinical cut off of 78 on the PDMS to indicate developmental delay. No infants in their sample of 71 were below this cut off at four months. A startlingly different pattern appears in the sample of six month old infants, (n = 50) where the mean for the supine sleepers' GMQ is in the "below average" range on the PDMS (85.7; sd 7.6; range 77 – 106), as is the FMQ (88.9; sd 9.0; range 77 – 109). Of this sample, 58% fell one standard deviation below the GMQ mean,

and 22% fell -1.5 standard deviations below the mean, that is, below the 78 point cut-off.[16]

The comparison between the supine sleepers in the Majnemer and Barr (2006) study and the supine sleepers in South Africa, who received no intervention, can be considered from one of two perspectives when considering pure statistical limits.[16]

1. According to the Canadian standard, 0% of the South African sample would be considered for therapeutic follow-up, as compared to 40% of the Canadian sample.

2. According to the South African standard, 12% of the South African sample would be considered for therapy, as would 58% of the Canadian sample.

However if the comparison is made by considering clinical judgement, irrespective of statistics, 22% of the Canadian sample compared with 12% of the South African usual care group would be considered for therapeutic intervention

In a comparison between the usual care infants and those involved in an international study of motor delay in infants who sleep in supine, it is interesting to note that far fewer individual infants in this country would be referred for therapy than in the international study. While as many as 40% of the infants in that study would be referred for therapy, only one infant in this sample (6%) would have been referred. This suggests that South African infants are not as delayed as their Canadian counterparts, but given the sample size of this study, it is not possible to generalise this to the larger population.

In the light of the fact that few of the infants in the group were found to be motor delayed, this programme may be more useful if implemented with high risk infants or infants who are in an institutionalised setting, who have greater need of a stimulation

programme. A future area of study could be the efficacy of the programme with populations who have poor developmental outcomes, for example premature infants who may have fewer opportunities to practice postural control skills because of a perception of fragility,[27] or with socio-economic groups who are at risk for developmental delay due to poverty.[55]

One future area of study pertains to the observation that the infants in the intervention group slept for longer in a 24-hour time span than their usual care counterparts. This suggests better self-regulation by these infants. Whether the programme has any effect on self calming and modulation of participating infants would provide an interesting course of future study.

5.5 Assessing the success of embedding the IPCP into the mother's Activities of Daily Living.

A point of concern is that very few diary pages were returned by the participating mothers, making it extremely difficult to assimilate this data. It was anticipated that the mothers would provide a clear picture of the use of the programme and that this could be correlated to the efficacy of the programme. This has unfortunately not been the case. While the programme is inferred to be effective based on developmental changes, there is still the possibility of a Type II error in the research findings because the actual implementation is difficult to gauge. One option to pursue in future research would be the use of an electronic diary data collector.[123]

An interesting point is that the use of diary pages is itself a confounding factor. This is because parents will usually check the pages before returning them and adapt their behaviour accordingly. Parents in both groups who had little time in prone play on the first diary set were susceptible to changing their behaviour based on what

they thought the expectation of the researcher would be. Therefore, merely by returning the pages the parents were affecting a change in their thinking and may sub-consciously or overtly have decided to increase the time spent in prone play on the days that they completed the diary. Had all or most of the parents completed the pages, confidence in the diary information would have been increased. This can be deduced from the fact that some of the diary pages submitted have no prone time at all throughout the diary sets, indicating that those mothers weren't consciously aware that they weren't incorporating prone time at all and therefore didn't change their behaviour.

A method of overcoming this is to blind the parents regarding which behaviours are being studied and to present a number of factors that may influence infant development into the questionnaires, diary pages and programme activities so that parents are not aware that an adherence to the 'prone to play' teaching was being studied. This blurring of the study focus would have had to have been consistent throughout the study design for both groups.

5.6 Summary

The IPCP which was designed and piloted in this study appears to have shown efficacy in improving motor development of infants who sleep in supine and are therefore at risk of motor delay. Limitations to the study have been identified, and these include a small sample size, a high loss to follow-up from the usual care group and difficulty in maintaining fidelity in the content and manner of what is taught by nursing sisters at Well baby clinics. These limitations increase the risk of a Type II error when concluding that the programme proved effective in this sample of infants. Generalisation of the study is also limited by the narrow social band represented by the sample.

However, randomisation of the sample, blinding of the assessor and the provision of uniform photosheets as a memory aid to mothers strengthen the veracity of the study in the provision of a programme which mothers can implement to reduce developmental delay. Data analysis suggests that this has been achieved. Significant differences in key areas suggest that infants in the intervention group were making progress in a manner which has been associated with good long term motor development. Infants in the usual care group showed a trajectory of development which places them at risk for early fine motor skill attainment, but which has been associated with poor long term outcomes for motor co-ordination and gross motor skill acquisition. There was a significant difference between the total motor quotients of the two groups, suggesting that the programme had had a positive impact on the intervention group.

CHAPTER 6 CONCLUSION

The definitive role of the development of postural control in the observable motor milestones of early infancy, toddlerhood, and indeed into the development of more complicated motor skills in childhood has been established by many studies.[124, 125] That this early body control is being compromised by the introduction of the BTS principle has also been set forth in this literature review. Numerous studies have sought to examine the effect of supine sleeping, and have established a definitive link between supine sleeping, a lack of prone play and developmental delay in infancy.[16] For the most part, doctors, nurses and therapists have advocated 'playing in prone' as a panacea for this problem.[5, 9, 20] However, mothers have difficulty in implementing this 'one size fits all' solution. A lack of understanding of how mothers construct their daily routines, and the need for an infant's developmental activities to be embedded into the activities which the mother needs to do is reflected in the 'prone to play' education campaign.

This study sought to develop a programme which allowed for exactly this level of embedding, with postures that would benefit the postural control of infants, enfolded into the daily routines of mothers. By making these challenging positions easily applicable to several activities, it was anticipated that mothers would more readily expose their infants to awake prone positioning, and thereby decrease their risks for developmental delay.

Occupational therapists in particular, through the study of the science of occupation, should take the lead in defining and disseminating how mothers construct the routines that guide their lives and make use of embedded activity to bring about improvements in the use of preventative programmes. If they believe that there is merit in a programme or intervention, analysis of how a family is to actively engage with the solution should be made before it is given.

Results from the testing of the usual care and intervention groups after the implementation of the programme suggest that the programme was effective with a sample of normally developing infants. Infants in the usual care group displayed patterns of development that suggest a risk for the failure of later gross motor skill acquisition, however, limited evidence of developmental delay was seen in this group at the time of testing.

6.1 Recommendations

The findings of this study have implications for occupational therapists who work in the field of early intervention. An earnest attempt needs to be made by therapists to design home programmes which can be enfolded into the activities which make up a family routine in order to improve the chances of the therapeutic intervention being implemented by the mothers. Further study into the efficacy of this IPCP with a broader range of infants and with a larger sample is warranted to determine whether it is a useful tool to use with infants at Well Baby Clinics. Its applicability to premature and high risk infants is also worth investigating, given the vulnerability of these groups to develop motor delay. Within the field of occupational science, continued understanding of how mothers enfold activities could be better studied through focus groups of mothers following the implementation of the programme.

Further study is also suggested by the finding that the infants in this intervention group slept for longer than their usual care counterparts. The potential role of a motor development programme for improved self-calming and regulation warrants deeper investigation.

Infants in this sample did not show as significant a level of delay as expected, but the sub-optimal patterns of development suggested by the data show that infants are still at risk of developing poor muscle

use and the long term effects of motor delay such as inactivity and poor motor co-ordination. Even mother-infant dyads that have economic advantages should be exposed to developmental programmes which allow a full exploration of motor achievement and normal developmental patterns in order to reduce long term risks.

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APPENDICES

Appendix A: Brainstormed activities and those modified in Pilot Study 1

The text on these tables appearing in black is what was originally sent to the four expert therapists. Their comments and recommendations made during Pilot study 1 have been inserted in two new columns and appear in blue

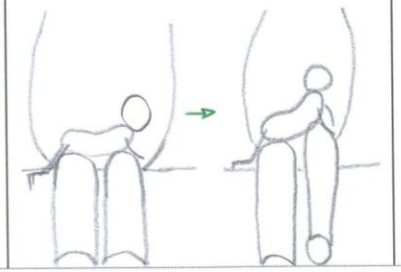
Summary of normal development related to postural control developed between 8 – 12 weeks:	
Eye control:	Limited visual accommodation,[89] limited tracking from side to midline , but starting to track across midline.[47] Convergence immature.
Head and neck:	Asymmetrical Tonic Neck Reflex more likely to be elicited in second month. Infant's head is not usually maintained in the midline position.[94] Head lag present.[47]
Supine:	Midline control of head and neck improving in supine and tracking with eyes and head improves.[47] Limited upper limb reaching forward to the midline in supine.[47] Head lag seen in pull to sit.[68]
Prone:	Head briefly lifted to 45° in prone extension.[47, 80] Chest off the surface.[80] Elbows held behind the level of the shoulders and baby is unable to draw them forward, therefore no weight bearing on the forearms.[80]
	Lower limb are more extended and hips are not dominated by the physiological flexion of birth.[47] Legs are also more active.
Sitting:	No unsupported sitting. When supported, back is still rounded with activation seen in the cervical musculature to enable baby to lift head and maintain a brief (5 second[93]) erect position and chin tuck. This facilitates visual tracking.[47]
Standing:	Month is characterized by a loss of weight bearing and disorganized behavior in standing. Loss of automatic stepping.[47, 68]
Locomotion:	Rocking and bouncing movements provide practice and strengthening. Movements are asymmetrical, rhythmic and repetitive.[47, 58, 89]
Grasp and reach:	Circuitous movements in the general direction of objects with incidental grasp.[47, 89] Release usually as a result of tenodesis rather than being intentional.[68] Reflexive flexion of the hand is reduced in the second month.[93] Reach and grasp are better if the head is stable.[53]

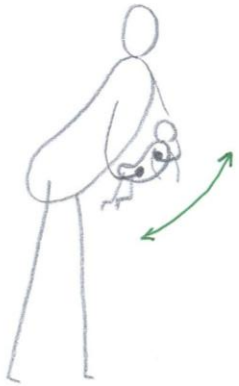
Exercise suggestions for 8 – 12 weeks (2 – 3 months)	Structuring/diagram	Anticipated part of Parent's ADL:	Therapist's comments	Activity accepted or rejected
•Pull to sit with mother's elbows stabilizing the pelvis for the infant.[87] – at every nappy change or clothing change	*Demo at this stage should show the parent's hands close to the shoulders, shoulders rounded with support for the neck 	Nappy changes and general lifting of the baby	Emphasise alternating sides. Concerned about the use of direct pull to sit – rather roll to the side and lift. Pull to sit shouldn't be taught to parents as it is a test.	Modified to roll to side and lift, with support at the head as necessary.
•Lying on mother's chest while mother is reclined on a pillow so that child looks up in extension to mom/at a mirror over shoulder.	Grading: lower pillow for Mom 	After feeds, to wind baby, during quiet play time.	Begin with Mom closer to vertical.	Accepted
•When infant is held at the parent's shoulder the supporting hand should be lowered to the baby's lumbar spine to facilitate a reactionary control.[108] Parent should drop their own shoulder too if the infant can maintain an upright position.		General carrying	Still need thoracic support when moving.	Accepted. Note inserted regarding movement

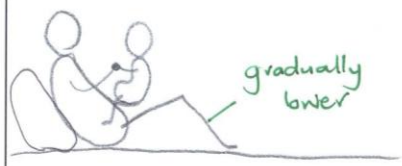
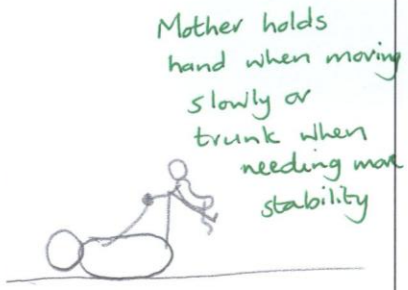
•Baby held using a 'rugby ball style hold that encourages extension. Parent's hand can be under head initially but is removed as child responds over time.		General carrying	Or parent can change the carrying angle.	Accepted.
•With the parent sitting with knees drawn up:[108] Start with baby lying on the semi-inclined knees and holding the baby's hands and forearms shift the baby into a sitting position. Maintain the sitting position for as long as the baby can sustain it without shifting the hands to the trunk to support the baby.	Structured with wedge or a receiving blanket under the baby's head and shoulders. 	Playing with baby and during calm alert time when Mom is making eye contact and talking to baby	Panel did not think this is a good activity yet – it is just enough to let the baby hold head in midline. Sitting is too hard. Very important to emphasize communication time. It would be better to use a peanut roll than a wedge.	Modified to exclude sitting position and include peanut roll.
•Baby held facing outward with the parent's one hand forming a seat and the other holding the infant against their body.[108] When the child begins to hold its own head the parent shifts		General carrying	Tilt the baby backwards so that the hip is in front of the pelvis to activate abdominal muscles too	Accepted.

the baby's body angle slightly outward so that there is more space between the parent's chest and the baby's back and head to encourage extension.				
•Parent's can gently stabilize the pelvis while the child in lying in prone to provide stability for extension. Hands on either side of the pelvis.[87] Mirror/face/pattern to attract the baby's attention and motivate extension.	Low foam wedge also to be provided. 	Baby's play time – 10 minutes suggested during the day	At this stage the roll under the shoulders is more important than pelvis stabilisation. Wouldn't use a special wedge – just a rolled blanket. Emphasize that the time is spread over the day.	Accepted, text modified to clarify timing.

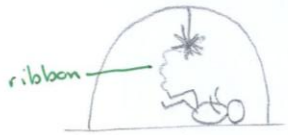
Summary of normal development related to postural control for 12 – 16 weeks:	
Eye control:	Visual tracking is nearly mature, but convergence remains immature until the end of the third month,[80] unless the head is stabilized.[68] Optical righting reflexes is better integrated.[47, 80]
Head and neck:	Control of head and neck is established in prone.[80] Body on head righting reaction is established in response to proprioception and tactile stimuli.[53] Optical righting reaction keeps eyes in position when body moves.[53]
Supine:	Chin tuck more easily maintained, head lag persists with pull to sit. Head actively maintained in midline when lying in supine.[47] Smooth control of head turning from side to side.[68]
Prone:	Baby can maintain some weight on forearms in prone with head held consistently at 45° and even upward toward 90°.[47] Head position can be maintained for at least a minute.[93] Baby able to bring elbows under shoulders and therefore weight bearing on the forearms is possible. Pelvis and thigh are flat on surface.[47, 93]
Sitting:	Supported sitting shows curvature of the spine lower down than previous months.[80] Baby mat attempt to hold head erect (30 seconds).[93]
Standing:	When placed in standing, the infant's legs are flexed with little active supporting, but some bobbing may be seen.[93]
Locomotion:	Early attempts at rolling in dispute in the literature. Some theorists state that baby may attempt prone to supine roll at this age,[80, 89] others consider it to be later.[94] Symmetry and the midline begin to play a role in all movement.
Grasp and reach:	Baby will hold firmly on to an object placed in its hand. May attempt to bring this to its mouth.[93] Baby may begin to make raking movements when in prone.[47]

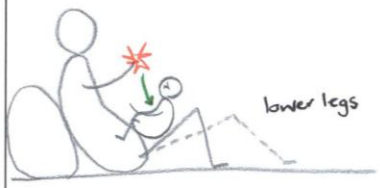
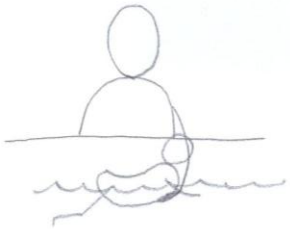
Exercises for 12 - 16 weeks (3 – 4 months)	Structuring	Part of parent's ADL	Therapist's comments	Activity accepted or rejected
•Pull to sit still, lowering back down to supine position. Still with stabilization and slow movements.	See first diagram	Still at each nappy change and general lifts off a surface.	No pull to sit – modified from side-lying.	Rejected in this form – incorporated in modified form.
•Position to play with a toy in side lying[108] with less and less support to encourage the balance between flexors and extensors. Reaching for a toy/pulling on a string that is attached to a rattle or mobile to create a noise (Actively place the string in baby's hand to have a cause and effect game).	Against cot or couch side or in the curve of Mom's leg. Head pillowed by wedge. 	While playing with baby, positioned to sleep.	Not a wedge, use a rolled receiving blanket or nappy.	Accepted
•Prone on parent's lap to wind the baby or just after that with a mirror/patterned toy to look at. Bring arms forward and even play at slapping on the surface below the level of the parent's thigh.[87]		Winding baby, calming or playing	Parents are unlikely to tip baby down as they will have reflux.	Accepted

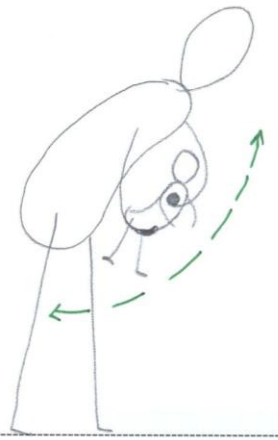
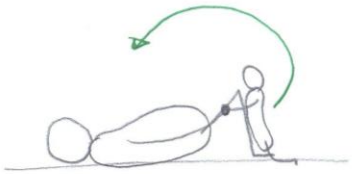
The lower Mom tips her thighs to lower the baby's head, the more extension is achieved, so nurses must show them that too much extension can be counter productive One of baby's legs can be between Mom's legs for dissociation.			Not aiming for dissociation yet so keep legs symmetrical.	
•Rugby ball hold continues but with less support.	E.g., move the hands across the shoulders. See first diagram	General carrying	Probably can't cope with less support yet.	Accepted
•With child facing outward with the parent's hand as a seat and other arm as a restraint, gently lean body forward and allow baby to swing gently away from parent's body.		Playing with baby, or carrying while doing household chores, watering the garden etc		Accepted

•With baby sitting in angle of parents body – parent lowers legs so that the pelvis and lower back of the baby has less support and the parent holds the baby's hands only to lower the support at the extremities.	Still with wedge behind baby's head 	Pull to sit while sitting on parents inclined legs should be structured into general play time. Gives an alternative to a snug-and-safe.	At 3 months you still don't need to move. Just hold baby's forearms and with your thumb in their hands and they will pull and work hard enough themselves. Leave out the wedge.	Modified
•Working on the principle of stretching the muscles that you want to use in the next phase – parent lies with legs bent and places infant on legs looking over the raised knees of the parent. Stability provided at the hips with gentle support. This will provide a stretch to the hip flexors that will encourage flexion at 4 months. Also encourages neck extension.				Accepted

Summary of normal development related to postural control for 16 – 20 weeks :	
Eye control:	Saccadic movements are more controlled. Visual tracking is essentially mature.[89] Improved convergence means that baby can watch own hands.[68]
Head and neck:	More purposeful, controlled movement on the basis of better trunk control. Increased head control in all planes results in better visual tracking and ocular control therefore baby can manage more object based motivators.[94]
Supine:	Head held in control throughout the pull to sit movement.[93] Baby begins to roll to side lying from supine with flexed legs/hips.[68] Need to encourage hands to face and mouth to encourage mouthing. Bilateral, symmetrical reaching can be expected to toys on the baby's chest.
Prone:	Holds head at 90° with ease.[68] Forearm weight bearing should be seen.[68] Begins to use pivot prone position (similar to 'swimming' stance). Rolling from prone to supine is incidental and largely due to a toppling over one shoulder.[93]
Sitting:	Head righting reflex allows head to remain still when body is tilted to the side.[93] No unsupported sitting as yet.
Standing:	Legs continue to flex when the infant is placed in standing, or fixes in extension,[68] but may show more vigorous bouncing.[93]
Locomotion:	Baby gives the impression of 'swimming' in prone, kicking legs and pulling with arms to attempt to move.[93]
Grasp and reach:	Hands grasped together in the midline and at mouth.[93] Grasping a cube with fist, no thumb opposition.[89, 91] Eye-hand co-ordination is improving to allow for a more accurate reach.[80]

Exercises for 16 – 20 weeks: (4 – 5 months)	Structuring	Part of Parent's ADL	Therapist's comments:	Activity accepted or rejected
•Encourage flexion and adduction of the hips initially by allowing the baby to lie on inclined legs and playing by 'cycling' the legs. Then provide resistance to the baby kicking into the parent's cupped hand.[90] Then encourage a lift and kick motion by tying a ribbon attached to a noisy mobile to the baby's foot so that the baby activates the mobile by kicking up. Also, position mobile to be kicked rather than reached	No wedge anymore?  	Part of general play and time on baby's back under a 'gym', or on the floor on a doughnut etc. Presented as another alternative to time in a chair.	No wedge should be needed any more.	Accepted.
•Pull to sit with one hand while the other stabilizes the abdominal muscles which allows the emerging chin tuck to 'lead' the movement.		Precursor to any lifting from surfaces.	Rather than pull to sit, hold baby's hand and forearms and lower from vertical to a cushion which is at 45°. If the baby tries to pull back up then guide the movement, if not then roll to side-lying, round and up to sitting again and then repeat. Alternatively, go from vertical toward 45° until child loses head control and then sit back up.	

•With baby lying on parent's inclined knees – track an object from baby's eye level to his tummy and when he is looking down with chin tucked then lower the legs slightly to force baby to maintain the posture.[90] Hold the hands as necessary.[87] (i.e. as close to the elbow or wrist as is necessary)		Playing with baby		accepted
•Spend some of bath time playing supported over parent's arm, but on the tummy. Swish baby back and forward only if they won't bob the head. Use the static posture to wash the back slowly so that the sensation of soap and sponge or facecloth on their backs can be considered.		Bath time	Queried the practicality of prone in water. After finding that all water play at bath time has a beneficial effect on motor development, these were rejected.	

•More active swinging in the prone position – parent's hand between legs over the lower abdomen and other hand from the side at the chest level and lean body out so that the arms offer a full range to swing baby.				Accepted
•Parent lies on back with knees toward the chest. Baby lies on the dorsal surface of the parent's legs. Parent raises lower limb from the knee until the tibia is parallel to the ground with the infant raised on the legs. Hold the baby's trunk so that they don't fall. Raise and lower baby from a 'standing' position to a 'flying' position in prone extension. The nearer the parents face the knees come the better the extension, but the greater the chance for the baby to slide forward!		During baby's play time		Accepted

•Sitting: parents sit on the floor and form an 'o' with their legs. Baby is supported by one leg[109] and the other leg of the parents is on top of the baby's outstretched legs to provide stability without actually holding the baby up.[108]		During baby's play time and during calm alert while presenting different toys.	The height of the mother's leg should be enough support. If the baby's shoulders are slightly behind the pelvis, the abdominal muscles will be activated. Must not hold the baby's legs down.	Modified
•When baby lies on tummy over parents knees encourage a rocking of the pelvis by alternately raising and lowering legs more quickly than in previous months.	See previous diagram		Not sure how much baby will tolerate this.	Rejected.
•When baby plays on back, play with a toy between baby's feet [90, 108] and bring it towards the hands, with the parent holding the ball/toy in position for baby.		Time when baby is on his back under a baby gym or mobile is time when Mom can be doing household tasks etc.		accepted

•When baby is lying down in supine, encourage him to move into a sitting position by rolling onto his side and apply pressure on the upper most hip or even on the shoulder or arm, while your hand under the opposite arm pit is lifting and twisting into a seated position.		Any time when play is over and you are moving to the next task, take a short time to practice this movement, or to practice rolling.	Too much for a 4 month old – move it later to approx. 6 months. This is a facilitated version of the roll to sit and the baby will not yet be able to complete it.	Moved and modified
•With baby lying sideways on Mom's lap, raise the leg that is under baby's chest and offer baby a toy above his chest so that he has to reach up to get it.[90]	Stretch weight bearing side, contract flexion laterally against gravity. 		You do not want trunk rotation until 6 months. Rather use a log roll on mom's lap so that baby can get used to the sensation.	Modified and also used later
•Guide baby to roll[108, 109] by bending his knee to waist level and carry it over his body and then wait for him to pull his chest level. As baby begins to twist, gently pull leg straight with the knee toward the surface.	Active flexion in side lying against gravity. 		No rotation at this stage.	Moved to later.

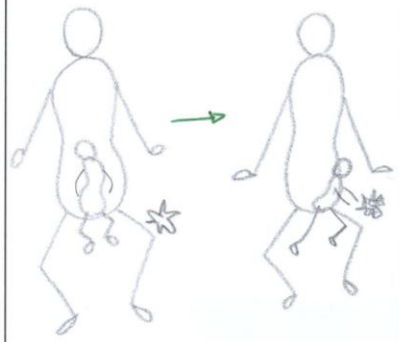
Summary of normal development related to postural control for 20 – 24 weeks:	
Eye control:	Essentially mature.[89]
Head and neck:	Chin tuck leads all movements in flexion. Tracking is mature.[68]
Supine:	Head control in supine is complete.[80] Baby can bring feet to mouth, thus elongating the head, neck, back and hip extensors.[94] Pull to sit shows active leading of the flexion by head.[93] When in supine the baby can reach for an object suspended above its chest.[93] Some theorists expect to see supine rolling into side-lying with activation/initiation of the movement by the abdominal muscles.[68]
Prone:	Other theorists expect to see rolling from prone to supine because of a collapse of the shoulders in weight bearing and a 'toppling over'.[93] Prone extension up onto straight arms and uses the flexors to stabilize weight bearing to rise up with more of abdomen lifted off the surface.[68, 93] baby can look down between the hands when arms are extended in prone.[68]
Sitting:	Most infants still require support in sitting, but some may precociously show unsupported sitting.[68] Baby may fix trunk in extension and lean on outstretched arms (tripod sitting).[68]
Standing:	Standing with support and holding on to objects to stand may start at 5 months.[91, 93] Taking own weight on legs and bouncing actively.[68]
Locomotion:	In side-lying, baby actively lifts head and laterally flexes the trunk which is a precursor for mobility.[68]
Grasp and reach:	Reaching for suspended objects is more purposeful, although not always successful.[93] Reaching is characterized by extension of the wrist and fingers.[68]

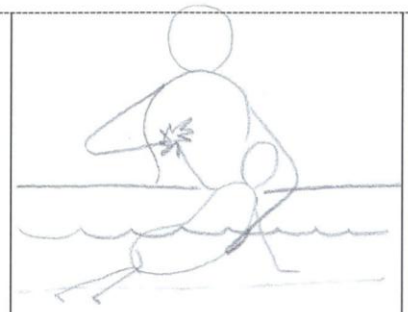
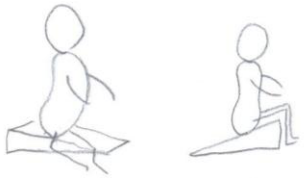
Exercises for 20 – 24 weeks: (5 – 6 months)	Structuring	Part of parent's ADL	Therapist's comments	Activity accepted or rejected
•With baby on its back: Place objects to the side of baby and slightly out of reach and encourage them to roll into side lying to get the object. Lift the leading leg to start the movement if baby won't roll. This is essentially using a body-on-body righting reaction.[53]		With baby lying on a bed while parent dresses or cleans or moves around the room	Lift both legs so that there is no rotation at the waist.	
•Playing row your boat:[87, 90] sit with baby on your thighs, almost at your knees, supported under the arms. Raise and lower the knees in a scissor action so that baby rocks side to side as you move. Now move the baby's shoulder slightly behind the hips and allow for a slight dip in the baby's shoulders as you rock. Baby's legs will come up to balance the movement as you facilitate the tummy muscles activation. *This one will need to be demonstrated because I can't describe it any clearer. The aim		During play time	If you tilt the baby's shoulders behind the pelvis you can rock to either side and you don't really need an unstable surface, just an angled one.	Accepted

is trunk flexion with an eccentric movement with hip flexion to raise the legs and neck co-contraction, maintaining chin tuck.				
•Pull to sit and lowering again still occurs at every nappy change.[109]		At all nappy changes etc		In modified format of moving though side-lying
•When dressing the baby roll the baby very deliberately to the side when needed to release clothing – don't just shuffle the clothes under baby. Lift the leading foot/knee and roll to the side.		Dressing tasks		Accepted
•Flying exercise can be increased to have baby higher on your legs so that his torso is over your knees. As you raise your legs to parallel and slightly higher baby has to work harder to keep body up. This may also elicit protective extension.[94, 109]	See previous diagrams	During baby's play time		Accepted

•Using mother's body as a roller: lying on your back, bring baby close to one side in so that she is leaning against your body with her tummy and with her legs folded under her. While holding the baby, you roll your body in the opposite direction so that baby goes up and over your torso. Guide baby's hands to the surface (floor/bed/mat) and gently rock so that baby has to take her weight on her hands and then off again. Play as you use your body to challenge her weight bearing skills.				Accepted
•In this position, if you offer baby a toy up and in front of baby so that she has to reach up and sidewards to get it you challenge her oblique tummy muscles.	*This should be an upgrade to a position that is closer to pivot prone. *i.e. movement simulates elongation on the weight bearing side and lateral flexion against gravity on the active side.	During baby's play time.		

Summary of normal development related to postural control for 24 + weeks	
Eye control:	Essentially mature.[89]
Head and neck:	Head control is complete. Trunk control allows for head extension in prone and antigravity flexion of head in supine without external stabilization with a hand.
Supine:	Successful supine to side-lying[68] and prone roll.[80] Active use of feet-to-hand play. Active use of hands to mouth to mouth objects for exploration and tactual learning.[68] Protective reactions in supine begin.[68]
Prone:	Prone is the most functional position with active extension, reach and grasp to front and side and pivot with lateral flexion of the trunk muscles.[47, 68, 94] Extension on straightened arms and reaching from forearm weight bearing position is seen.[93] When pushing up, fingers are generally extended too.[93]
Sitting:	If an adult holds the hands of an infant it will most likely pull itself to sit.[93] Unsupported sitting considered normal by some theorists[89] while others push this out to 8 months.[80] General consensus appears to hold this at 5 – 8 months.[53, 68, 91]
Standing:	Infant may be standing while holding on to objects.[89] Hips are still not fully extended.[68]
Locomotion:	Baby is moving in pivot prone through a wide range of movements and able to pursue objects that are within the same plane in this manner. Baby may also push up to four-foot kneeling (crawling) position.[68]
Grasp and reach:	Emergence of asymmetrical, reciprocal and dissociated movements result in better stabilization proximally with dissociated movements of limbs. Reach with one hand while stabilizing posture with the other allows for reaches in sitting.[89] Grasp is primitive[93] and palmar with the radial side of the hand leading the movement.[68, 80] Therapists Comments: The milestone descriptions in general are too advanced for a nursing sister. Need to describe what is being seen in clearer language.

Exercises for 24+ weeks until reassessment.	Structuring	Part of parent's ADL	Therapist's comments	Activity accepted or rejected
•Sit with baby between your outstretched legs and put the toys that baby is attracted to on the outside of your legs so that baby reaches over your leg to play with them. Help baby to reach and twist at the shoulder to do this. When she is in a kneeling position then tuck her knees under her hips so that they are getting used to bearing her weight.[90]			You move with the baby and tilt your body to facilitate reach. Move the toy to attract attention.	Accepted
•Encourage a lot of hand to foot play by tying various interesting rattles, scrunchies, bells and tassels on the foot and allow baby to play with both hands to one leg and with foot into mouth so as to straighten the leg.	See previous picture			accepted

•Use side supported position in the bath, with baby lying sideways over your arm and playing with the water and reaching for toys above baby's shoulder, with the baby's lower arm close enough to the bottom of the bath to encourage pushing up and weight bearing[90]		Bath time		Bath activities removed
•Continue to play over Mom's side as if she were a roller. Encourage alternate weight bearing by rocking baby to touch her hands to the floor and the moving back to touch her feet to the floor. The faster you do this the more support baby will need, but the more fun it can be for baby. Use the element of surprise by moving suddenly within the game and or counting to move.	As per previous month			
•Vary baby's sitting challenge by sometimes sitting her on the wedge with her legs down the slope (i.e. with the bottom sitting on the highest part of the wedge) and sometimes with her bottom at the lowest part of the wedge and her legs over the				

edge. This will result in a different challenge to her tummy and back muscles each time. Be more protective with extra cushions around her when you use the wedge to sit on as she may initially be more unstable				
•Have baby sitting over your leg as you sit in long sitting.[87] By varying the position of baby leaning against the opposite leg you can get her into kneeling or even standing on one leg. Make sure that she is taking some weight in each position. If she is wobbling in standing put your hand over her hip with your fingers supporting her hip bone and your thumb supporting her bottom.			Again, emphasis on mother's movement to direct the play.	
•Back lying under a gym or mobile to reach for ~~and~~ kick is still very important.		Play time when Mom needs to be busy for example lying on the bed while she folds laundry etc.		

•Baby should tolerate more and more tummy time without needing as much input to motivate him to stay on his tummy. Use really attractive and favourite toys, mirrors and pictures of people's faces to motivate him to spend time on his tummy.[108]	All of these are part of more active play with the baby and less part of taking care of the baby. This may have varying participation by those Moms who have returned to work.	Active play		

Appendix B 1: Photo-sheets for age band 2 – 3 months, page 1

(All of the photo-sheets are reduced to allow for binding)

Appendix B2: Photo-sheets for age band 2 – 3 months, page 2

Appendix C1: Photo-sheets for age band 3 – 4 months, page 1

Appendix C2: Photo-sheets for age bands 3 – 4 months, page 2

Appendix D1: Photo-sheets for age band 4 – 5 months, page 1

Appendix D2: Photo-sheets for age band 4 – 5 months, page 2

Appendix E1: Photo-sheets for age band 5 – 6 months, page 1

Appendix E2: Photo-sheets for age band 5 – 6 months, page 2

Appendix F1: Photo-sheets for age band over 6 months, page 1

Appendix F2: Photo-sheets for age band over 6 Month, page 2

Appendix G: Information page and consent form: Nursing sisters

Dear Sister,

Re: Proposed Research into Infant Development Programme

Hello! My name is Beverley Hewson and I am a qualified Occupational Therapist working in the field of paediatrics. I am currently doing research for my Masters degree in Occupational Therapy and it is in this regard that I am sending this letter to you today.

As you may be aware, since the "Back to Sleep" education campaign to reduce Sudden Infant Death Syndrome was introduced, researchers have found that babies who sleep on their backs or sides are more likely to have delays in rolling, sitting and crawling. As a result parents are advised to make sure that their babies have 'tummy time' in play. I would like to test a programme that I have designed, in which parents can use day-to-day tasks with the baby to incorporate 'tummy time' making it easier for them and hopefully more achievable.

However, I feel that it is important for mothers to be empowered by such a programme, and not to feel that it is a 'remedial intervention', which is what they may feel if it is presented by a therapist. No new mother wants to feel that their child must do a therapy programme in order to be 'normal'. However, the clinic sister is a natural and comfortable source of child development information. Mothers participate in programmes that the nursing sisters give them with ease. It is for this reason that I feel that clinic sisters who run 'well baby clinics' are in the perfect position to be trained in this programme, which they in turn could teach to the mothers, who are willing to participate, in testing the programme.

What I propose to do is to ask you to hand out information letters to any mother coming to the clinic for their child's 8 week visit. The letter would include a permission slip which the mothers would fill in and sign. They would then leave it with you, the clinic sister, for me to collect later in order to contact the mother to arrange an appointment with her.
The information sheet is worded in such a way that if a mother does not wish to participate, she can feel assured that the clinics services will not affected be by her decision.

Should you agree to participate, this would involve your clinic being assigned, by random process, to either the control group or the experimental group.
If your clinic falls into the control group, then you will not run the programme for the mothers, but will provide the vital data for comparison to determine whether the

programme works. You will be asked to weigh the babies on a monthly basis and to give the mothers the Baby's Day Diary to complete for that month, at each visit.
If your clinic is assigned to the experimental group, then the mothers under your care will be doing the programme with their infants and you are asked to attend a short training session on the programme and are asked to teach the new activities to the mothers at the first visit and monthly thereafter until the programme ends (i.e. for 4 months). You would also give the mothers the Baby's Day Diary to complete for that month at each visit.

Should you agree to participate, please sign the attached Consent form? Please also feel free to contact me with any queries or comments that you may have.

Thank you for your time and consideration in this regard.
Yours truly,

Beverley Hewson
Occupational Therapist

Consent Form

I have read the proposed study letter and agree to participate in the research by giving the information letters to mothers who attend my clinic for their babies' 8 week check up. Should I fall into the experimental group, I agree to attend a short training session at a time that is convenient to me.

Practitioner's name: …… Signature: ……

Date: ……..

Appendix H: Information sheet and consent form – Usual care group

Research: Supine sleeping infant milestone achievement

Dear Parents,

Congratulations on the birth of your baby! I am an Occupational Therapist with an interest in infant development, and I am currently doing research toward a Masters degree in Occupational Therapy at the University of Witwatersrand. I would like to invite you and would be most grateful if you would consider participating with your baby in the research study on infant development that is outlined below.

Why is this study important? *In the last 15 years doctors and nurses have taught parents the value of putting their babies to sleep on their backs in order to reduce the risk of Sudden Infant Death Syndrome or Cot Death. But a less publicized part of the "back to sleep" campaign is that infants should be placed on their tummies to play.*

During this time however, it has been noticed that babies who sleep on their backs may have delayed gross and fine motor milestone development. It is thought that most normally developing children will catch up this delay by 15 – 18 months of age. In this research I am looking into the effect of positioning on infants who sleep on their backs or sides.

Please be aware that participation in this study is voluntary. Should you decide not to participate you will still receive the services and support that you seek from this baby clinic and its staff. Should you choose to participate, but decide at a later stage to stop, you may do so without any concerns about loosing the support of the clinic or its staff.

How will the study be done? *The study will run from the time that your baby is 8 weeks old, until they are approximately 6 months old. At that time all of the babies in the study will be assessed to see if they have any gross or fine motor delays.*
During the 4 months of the research parents will be asked to complete a diary for 3 days each month. This diary uses shading blocks to record what was happening through the day and should take approximately 20 minutes to fill in each day.
You will be given advice from (the sister/midwife's name) that she normally gives moms on positioning and stimulation. You will also be contacted on a monthly basis by the researchers in order to collect that month's diary pages.

Are there any benefits? *Yes. Should your baby show any milestone delay, this will be noted early in his or her life and early intervention may then be of benefit.*

Are there any risks? *Foreseeable risks to yourself are that you may find the completing the diary to be too much to do in this busy stage of your family's life.*

What happens if my baby has delays? *If there are any worrying delays in your baby's development at six months, you will be contacted and given feedback regarding these problems and can be referred to paediatricians and therapists who will be able to assess and treat the problem.*

Confidentiality: *Confidentiality regarding results will be maintained by assigning codes on result papers, rather than using names. For this study I will need some background information for your family, and your contact details in order to collect diary pages, and to arrange for the initial and final assessments. Only one list will be made to link the babies names to the test scores so that feedback can be given should the need arise. This list will be secured by the researcher.*

If you have any queries or require any more information, please feel free to contact me on (011) 781 – 0191, or 083 448 0999.

If you are happy to participate, and have your baby participate in this study, please read and sign the attached consent form and information questionnaire.

Thank you for your time in this regard,

Beverley Hewson
Occupational Therapist

Consent Form

I have read the proposed study letter and agree to participate in the research. I also give permission for my baby to be included in this research, as outlined in the information sheet attached.

Parent's name: …… Signature: ……

Date: ……..

Contact Details

Please supply your contact details so that the therapist can contact you in order to make the appointment for the initial assessment of your baby:

Parent's name: ……

Home telephone number: ……

Cellphone number: ……

Address: ……

……

……

Appendix I: Information letter and consent form – Intervention group

Research: Supine sleeping infant milestone achievement

Dear Parents,

Congratulations on the birth of your baby! I am an Occupational Therapist with an interest in infant development, and I am currently doing research toward a Masters degree in Occupational Therapy at the University of Witwatersrand. I would like to invite you and would be most grateful if you would consider participating with your baby in the research study on infant development that is outlined below.

Why is this study important? *In the last 15 years doctors and nurses have taught parents the value of putting their babies to sleep on their backs in order to reduce the risk of Sudden Infant Death Syndrome or Cot Death. But a less publicized part of the "back to sleep" campaign is that infants should be placed on their tummies to play.*

During this time however, it has been noticed that babies who sleep on their backs may have delayed gross and fine motor milestone development. It is thought that most normally developing children will catch up this delay by 15 – 18 months of age. In this research I am looking into the effect of a series of activities that parents can do with their babies to see if this delay can be prevented or reduced. The purpose of the activities is that they should be easy to carry out and part of the normal daily activities of the parents, but challenging enough for the baby's developing muscles to be effective in developing posture control.

Please be aware that participation in this study is voluntary. Should you decide not to participate you will still receive the services and support that you seek from this baby clinic and its staff. Should you choose to participate, but decide at a later stage to stop, you may do so without any concerns about loosing the support of the clinic or its staff.

How will the study be done? *The study will run from the time that your baby is 8 weeks old, until they are approximately 6 months old. At that time all of the babies in the study will be assessed to see if they have any gross or fine motor delays.*
During the 4 months of the research parents will be asked to complete a diary over 3 days each month. This diary uses shading blocks to record what was happening through the day and should take approximately 20 minutes to fill in each day.
Each month when you attend the well baby clinic to have your baby weighted, the nursing sister will teach you the new activities and exercises to do with your baby in that month.

The activities you will be given to do with your baby are intended to be part of the normal routine, of caring for, feeding, dressing, playing and interacting with baby, that would be done in the course of a typical day. They may take a little extra time, but will also help to focus some of your interaction with your baby, so hopefully they will be enjoyable to both of you!

Are there any benefits? *Yes. Should your baby show any milestone delay, this will be noted early in his or her life and early intervention may then be of benefit.*

Are there any risks? *Foreseeable risks to yourself are that you may find the completing the activities or diary to be too much to do in this busy stage of your family's life.*

What happens if my baby has delays? *If there are any worrying delays in your baby's development at six months, you will be contacted and given feedback regarding these problems and can be referred to paediatricians and therapists who will be able to assess and treat the problem.*

Confidentiality: *Confidentiality regarding results will be maintained by assigning codes on result papers, rather than using names. For this study I will need some background information for your family, and your contact details in order to send activity sheets and collect diary pages, and to arrange for the initial and final assessments. Only one list will be made to link the babies names to the test scores so that feedback can be given should the need arise. This list will be secured by the researcher.*

If you have any queries or require any more information, please feel free to contact me on (011) 781 – 0191, or 083 448 0999.

If you are happy to participate, and have your baby participate in this study, please read and sign the attached consent form and information questionnaire.

Thank you for your time in this regard,

Beverley Hewson
Occupational Therapist

Consent Form

I have read the proposed study letter and agree to participate in the research. I also give permission for my baby to be included in this research, as outlined in the information sheet attached.

Parent's name: …… Signature: ……

Date: ……..

Contact Details

Please supply your contact details so that the therapist can contact you in order to make the appointment for the initial assessment of your baby:

Parent's name: ……..

Home telephone number: ……

Cellphone number: ……..

Address: ……

……

……

Appendix J: Plagiarism Declaration & Ethical Clearance Certificate

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Hewson

CLEARANCE CERTIFICATE	**PROTOCOL NUMBER M070831**
PROJECT	The Effect of Developmental Activities Embedded into Parents's Activities of Daily Living, on Supine Sleeping Infant Milestone....
INVESTIGATORS	Mrs B Hewson
DEPARTMENT	Occupational Therapy Dept
DATE CONSIDERED	07.08.31
DECISION OF THE COMMITTEE*	APPROVED subject to changing 'can' to 'may' in the benefits statement in the information sheet

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.

DATE 07.09.03 **CHAIRPERSON** .....
(Professors PE Cleaton-Jones, A Dhai, M Vorster, C Feldman, A Woodiwiss)

*Guidelines for written 'informed consent' attached where applicable

cc: Supervisor : Mrs D Franszen

DECLARATION OF INVESTIGATOR(S)

To be completed in duplicate and **ONE COPY** returned to the Secretary at Room 10005, 10th Floor, Senate House, University.
I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. **I agree to a completion of a yearly progress report.**

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Postgraduate Office, Faculty of Health Sciences
Wits Medical School, 7 York Road, PARKTOWN, 2193, Johannesburg • Tel: (011) 717 2745 • Fax: (011) 717 2119 • e-mail: healthpg@health.wits.ac.za

PLAGIARISM DECLARATION TO BE SIGNED BY ALL HIGHER DEGREE STUDENTS

SENATE PLAGIARISM POLICY: APPENDIX ONE

I BEVERLEY HEWSON (Student number: 9403078M) am a student registered for the degree of MASTERS IN OCCUPATIONAL THERAPY in the academic year 2010.

I hereby declare the following:

- I am aware that plagiarism (the use of someone else's work without their permission and/or without acknowledging the original source) is wrong.
- I confirm that the work submitted for assessment for the above degree is my own unaided work except where I have explicitly indicated otherwise.
- I have followed the required conventions in referencing the thoughts and ideas of others.
- I understand that the University of the Witwatersrand may take disciplinary action against me if there is a belief that this in not my own unaided work or that I have failed to acknowledge the source of the ideas or words in my writing.

Signature: B Hewson Date: 24-08-2010

Appendix K: Biographical Questionnaire for all parents

Supine Sleeping Infant Milestone Achievement Questionnaire

Code _____ [For office use]

1. *Baby's first name: .....*
2. *Baby's Date of Birth: .....*
3. *Is this your first baby? ☐ Yes ☐ No*
   If not, how many other children in the family? .....

Baby's details at birth:

4. *Baby was born at ..... weeks.*
5. *Birth weight ..... Length .....*
6. *Apgar scores .....*
7. *Were there any problems with the baby at birth? (for example: blue baby, delayed breathing, poor sucking, floppiness, prolonged foetal distress, etc) ....*
8. *Baby was born at .... (specify which hospital/clinic/maternity unit)*

9. *Are you intending to attend a Mom's and Tots group/Clamber club group or any similar group that would be running a motor development programme for your baby in the next 4 months? ....*

10. *In what position is Baby put to sleep MOST of the time? Please tick:*
    - ☐ *On Back*
    - ☐ *In Side-lying – In foam supports? ☐Yes ☐No*
    - ☐ *On Tummy*
    - ☐ *No fixed position*
    - ☐ *A combination of side and tummy-lying*
    - ☐ *A combination of back and tummy-lying*
    - ☐ *A combination of back and side-lying*
    - ☐ *Other: Please specify:*

    _____
    __

    _____
    __

11. *On whose advice have you made the decision to position your baby in this way while he/she is sleeping? (Tick as many as are applicable)*
    - ☐ *Hospital staff*
    - ☐ *Midwife*
    - ☐ *Antenatal/postnatal classes*
    - ☐ *Clinic sister*
    - ☐ *Advice from family members (Mother, sister, aunts, grandmother etc)*
    - ☐ *Advice from other new mothers I have contact with*
    - ☐ *Read the advice in books*
    - ☐ *Read the advice in a Baby magazine*
    - ☐ *Read the advice from internet search*
    - ☐ *Other: Please specify:*

    _____
    _____
    _____
    _____

12. *Who is involved in the daily care of the baby?*
    - ☐*Mother*
    - ☐*Father*
    - ☐*Grandparent*
    - ☐*Au pair/Child minder*
    - ☐*Crèche/day care/day mother*
    - ☐*Other: Please specify:*

    _____
    _____
    _____
    _____

Thank you for your time in completing this questionnaire!

Appendix L: Training manual for nursing sisters (2 – 3 months). Subsequent months available on request.

Exercise Guide to the Baby's Postural Control Programme

Training Guide for Well Baby Clinics

The following exercises are intended to become part of a 'tool box' of activities that a Mother can do with her baby in order to challenge the development of the postural muscles of her infant.
Mothers can be taught the exercises and suggestions can be made regarding how to incorporate the activities, but the most effective use of any programme is achieved when a mother starts to use the exercises in different positions and in ways that are applicable to her circumstances, resources and time.

Baseline principles:

ᔓ It is very important that Mom and baby have fun if they are playing and working together. It is important to stress this as Mothers learn an exercise programme – emphasise the fun of time together and the potential for bonding, rather than have the focus of the activities on achieving milestone development.

ᔓ It is very important to teach the Mothers to watch their baby's faces – signs of distress and fatigue should be a cue to stop and try the activity again at another time (or in a few weeks time if baby consistently refuses a task).

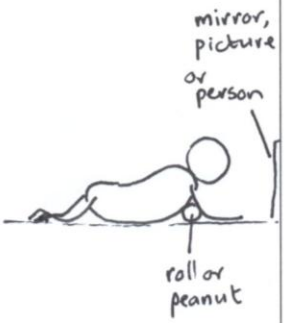
ᔓ The slower the movements that Mom makes when moving the baby through transition positions, the more muscle control is needed by the baby. A good example of this is the side-lying to sit position (see 2 – 3 months).

(ᔓ The faster the movement the more it will get the babies attention and add to the fun of the activity but then Mom needs to be more supportive motor-wise and more observant of baby's face for signs of distress.)

ᔓ When Mom is moving, the baby will need more support than when she is static, and so some activities should be modified if Mom starts to walk. An example of this is the 'at the shoulder' hold in the 2 – 3 month group. When standing, Mom can lower her hand toward the lumbar and sacral spine of the baby, but when walking will need to provide support over the thoracic spine of the baby (see photos of 2 – 3 months).

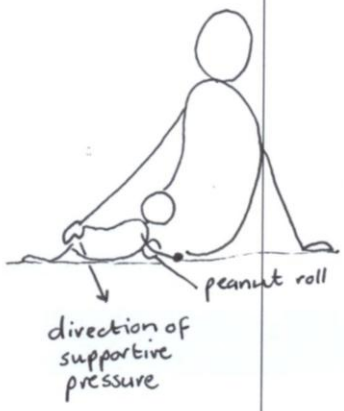
ᔓ I think that it is important for mothers to carry their babies rather than place them in car seats, bumbo seats or prams. Carrying baby is one of the best ways to involve baby, stimulate language as you tell them what you are doing and, of course, challenge their muscles. Try to encourage the Mothers in the programme to carry their babies as much as possible.

2 months – 3 months

What we hope to see at this age:	Supine: Midline control of the head and neck is improving when baby is on his back so that baby can track an object from side to side with his head and his eyes. Because this is difficult to maintain, baby will most often lie with head to one side. Prone: He has some difficulty in lifting his arms up to the midline when lying on his back. When on his tummy he lifts his head briefly about 45°, but his head bobs in this position. His legs are flatter on the surface and more of his upper thigh is in contact with the surface when lying face down.		
Exercise suggestions	**Diagram/Notes:**	**When will Mom use this?**	**Can it be made more challenging?**
1) Side-lying to sit Starting position: baby on back With hands around baby's trunk, roll baby onto her side and then lift her upper body toward you. Move slowly so that her head has time to respond. Once you see her head lifting toward her shoulder, gently bring your hands level to move her trunk to a sitting position. Now pick baby up into your arms.	Don't pull on baby's arm. Hand supports the shoulder wing. Photos 1 – 4 of your sheets show this in the best manner	Any time Mom lifts the baby	The slower Mom moves (within reason of course) the more work the baby has to do.
2) Tummy time at nappy change Starting position: baby on back Once the nappy change is complete roll the baby onto her tummy on the change mat. Put a rolled nappy or receiving blanket under the baby's chest and arm pits, so that the arms and elbows are forward, with the hands to the middle (mouth). If baby is unhappy, try to settle her with your voice and support her bottom with slight pressure before giving up. Max time initially 1 – 3 min. Lengthen the time as baby gets older.	Good motivators here are mirrors, pictures of babies and photo's of mom.  Remind Mothers never to leave the baby unattended on a compactum or bed.	After every day-time nappy change	As baby can cope: remove nappy (under the chest) and gradually lengthen time

Exercise suggestions	Diagram/Notes:	When will Mom use this?	Can it be made more challenging?
3) Lying on Mommy's inclined legs Starting position: Mom has her legs bent at an incline and baby lies on her legs with his legs on her tummy. Roll a nappy like a peanut (has instructions on the photo sheet) to support baby's head. Practice looking to the side and returning head to midline. Practice maintaining eye contact (which is hard for baby at this stage).		Anytime! After feeds, after sleep, before sleep to rock baby ...etc	Start moving the object a few degrees from the midline, and increase to 180° as baby masters head control.
4) Lying in prone on Mommy's chest Starting position: Mom lies back against some cushions or on a couch with the baby lying on her chest. Bring baby's arms forward so that his hands are near his mouth and his elbows are tucked in.		Any time! Burping baby, between sides of a breast feed, comforting baby etc...	As Mom lies back more (toward vertical) baby has to work harder. The more upright Mom is, the easier it is for baby. So if Mom is using the position to comfort baby she should be more upright so that the position doesn't add to baby's lack of stability.
5) Holding baby up to Mommy's shoulder Starting position: baby is held in Mom's arms facing her shoulder. When Mom is standing or sitting still she can make use of the opportunity to practice head control by sliding her hand slightly down her baby's body so that the baby has to work harder to maintain head control. As soon as baby's head starts to bob out of control, then stop, or even move your hand back up a few centimeters.	This is more for when mom is stationary. As soon as she starts to move the baby will need support in the thoracic area of her back. 	General carrying and holding.	

6) Holding baby facing outwards Starting position: baby upright with his back toward Mom's chest. Her hands support under his bottom and at his chest. In this position Mom can practice head control to the midline (visual tracking from side to the middle). Baby's hands to the middle/chin/mouth.	This is not a good position for an over stimulated baby. 	General carrying and holding.	As the baby gets stronger, Mom should angle his body away from hers so that there is a little gap between his head and her chest so that he has to exercise his muscles to keep his head up.
7) Holding baby like a 'rugby ball' Starting position: baby lies over Mom's arm so that his body is tucked into her side Mom uses her other arm to support the weight of baby's chest and head. Mom's arm acts as a stabilizer for a little bobbing head.		General carrying and holding.	Don't really want to make this any harder at this stage.
8) Holding baby against your side. Starting position: with baby slightly curled against Mom's side. The arm that is on the side that baby is tucked into is curled around baby's shoulders to bring the baby's hands to the middle. Mom's hand is holding the outer leg of baby toward its own chest (i.e., baby's leg is bent)	Mom's other hand can either be free, or it can be under baby's bottom for extra support. This position should look very rounded and contained. 	General carrying and holding.	
9) Playing on tummy Starting position: baby on tummy Put a rolled nappy or receiving blanket under baby's chest and armpits. If baby fusses try supporting him at his nappy – just a little pressure with your hand.	Encourage Moms to get down on the floor with baby. You can verbally point out to Mom's that the toy in the photograph is TOO HIGH.	Short frequent intervals in a variety of settings during the day.	Don't try to make it too hard at the moment – rather build trust that you will rescue baby from an un-comfortable position. So if Mom has tried to lift baby's chest and also supported him over his nappy and he is still unhappy, rescue him and try again later.

Make lots of effort to motivate baby – lean your face down, or place a mirror or have someone else in front of him to motivate him. Lie baby on the bed on his tummy so that you can sit on the floor to motivate him to look up. Baby will only cope with 1 – 3 minutes on his tummy at a time, so use short, frequent stops in this position throughout the day.			
10) Playing in side lying Starting position: Mom sits with her legs stretched out in front of her and bends one knee to make a curve. Baby lies on his side against her leg. Play with baby for as long as he is happy, using Mom's face as entertainment or noisy toys etc. Remember to alternate sides for baby	The sensation of lying on his side prepares baby for rolling and causes him to practice a balance between front and back muscles. 	Playing with baby	No upgrade in this position, but baby will roll in and out of this position and progress to playing over the Mother's legs.
11) Standing baby Starting position: With her baby well supported under his arms, Mom lifts him into standing on her legs Some baby's don't like the feeling of weight bearing on their feet and so may lift their feet up – teach the Moms to try again another week. Don't use baby's upper arms or forearms to pull him into standing at this stage – he will just learn to cheat and use the wrong muscles to keep himself upright.	This position is particularly self explanatory and its inclusion is really to remind Mother's to use standing, long before their infants are mobile. It is important however, to support the baby at the trunk and not the hands. 	Playing with baby.	Natural progression of bouncing and 'hopping' the baby to increase weight bearing in the legs in keeping with the progress of head, neck and trunk control of the baby.

Appendix M: Copyright agreement for Baby's Day Diary©

B.C. RESEARCH INSTITUTE FOR CHILDREN'S & WOMEN'S HEALTH

Centre for Community Child Health Research (CCCHR)
L614 - 4480 Oak Street
Vancouver, B.C. Canada V6H 3V4

BABY'S DAY DIARY COPYRIGHT AGREEMENT

Name of Researcher(s): MRS BEVERLEY LOUISE HEWSON

Address: 34 VICTORIA STREET
KENSINGTON 'B', 2194
GAUTENG
SOUTH AFRICA

For using the Baby's Day Diary© or any of its modified versions, the researcher(s) agree as follows:

- Acknowledgments will be made for using the Baby's Day Diary© should results be formally published in a scientific journal, citing:

  - Barr RG, Kramer MS, Leduc DG, Boisjoly C, McVey-White L, Pless IB. Parental diary of infant cry and fuss behaviour. Arch Dis Child 1988;63:380-7.

  - Barr RG, Kramer MS, Pless IB, Boisjoly C, Leduc D. Feeding and temperament as determinants of early infant crying/fussing behavior. Pediatrics 1989;84(3):514-21.

  - Hunziker UA, Barr RG. Increased carrying reduces infant crying: a randomized controlled trial. Pediatrics 1986;77(5):641-8.

- **Please sign this form and mail a signed original to:** Dr. Ron Barr, Director, Centre for Community Child Health Research, 4480 Oak Street, L411A, Vancouver, B.C., Canada, V6H 3V4

BEVERLEY HEWSON	BHewson	2-08-2007
Name Researcher	**Signature**	**Date**
Name Researcher	**Signature**	**Date**
Name Researcher	**Signature**	**Date**

Please also keep a signed copy for your own records.

Baby's Day Diary Copyright Agreement
March 2006

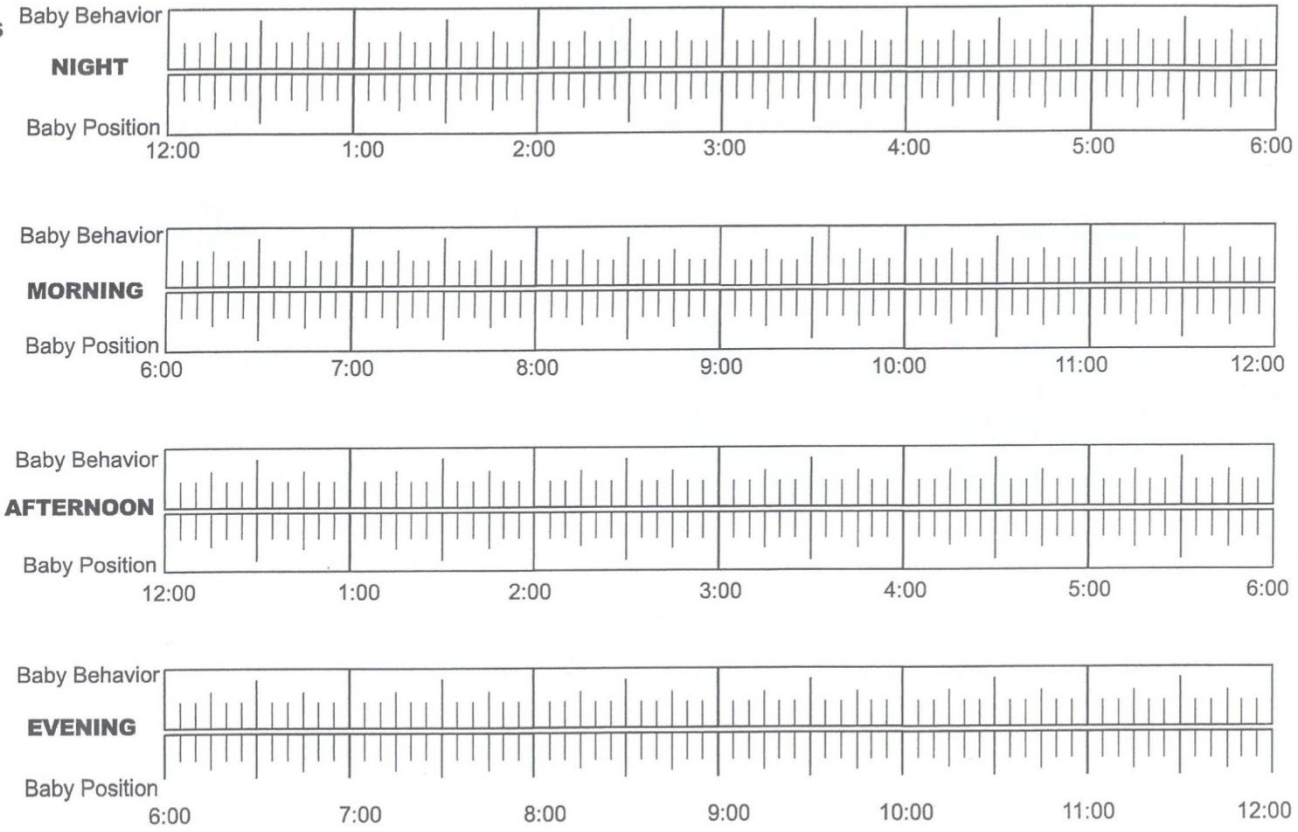
Appendix N: Baby's Day Diary© Day 1 (of 3): intervention group

DAY 1 **Date** _____ **Name** _____

Please check that the rulers are completed with baby behaviors and positions throughout the day.

Baby Behaviors

- Sleeping
- Awake
- Feeding
- Cannot Remember



Baby Position when AWAKE

- Hold or Carry
- Sitting with Support (for example car seat, carriage)
- Sitting without Support
- Lying on Back or Side
- Lying on Front

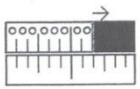
Please mark position of baby on top of ruler each time baby is put down to sleep or for a nap.

Position Markers:

↑ = baby on back, face up

↓ = baby on tummy, face down

→ = baby on side



Baby on side when put down.

Was this a typical day? Yes ☐ No ☐

If no, please explain _____

The Baby's Day Diary Training Script

*[Note: These instructions are meant to be **explained verbally** to caregivers in order to help them understand the logic of the Baby's Day Diary as well as to give them guidelines for completing the codes.]*

INTRODUCTION:

As mentioned on the consent form, you are being asked to complete *[number of days as specified by the study]* of the diary when your baby is *[age as specified by the study]*.

Let me show you how to fill the Baby's Day Diary. *[Take out the diary book]* First of all, don't panic! The diary may look quite complicated, but don't worry, it is not!

The diary is used to record your baby's behaviours such as feeding, sleeping, crying and other common activities. There are two pages of instructions at the back, plus I'm going to go over it quickly with you now.

We do **not** expect you to fill in the diary minute by minute. The goal of the diary is to have a general picture of your baby's behaviours during the course of a day. Parents usually find it easiest to fill in the diary every 2-3 hours, or at the same time as a frequent activity like feeding or changing their baby.

The only thing you are asked to do is fill in the date and the blocks of time on the diary with the available Baby and Parent Codes and Events.

To make your task a little easier, the entire day is represented in 4 "rulers", each one represents 6 hours of time: for night (midnight to 6 am), morning (6 am to noon), afternoon (noon to 6 pm), and evening (6 pm to midnight). The rulers are divided in half, with Baby codes along the top and Parent codes along the bottom.

It is not necessary to describe any activity that lasts less than 5 minutes. Most of the behaviours that we will be interested in will last at least 5 minutes (like fussing and crying), and often will last hours (like sleeping).

BABY CODES:

The codes representing your baby's behaviours appear on the left side of the Baby's Day sheet. *[Use Example and Practice Diary page. Point these out to the mom and read them.]* These are behaviours your baby will repeat throughout the day and night. When you enter these symbols onto the time "ruler", it lets us know when and for how long these behaviours happen.

So, let's actually go over it. First you would write in the date. *[demonstrate this]*. Then you would fill in the **Baby Codes**. In this example, this baby slept from midnight to 1:15 am: A

vertical line was drawn at midnight and at 1:15 on the baby ruler and then filled in with the *Sleep* symbol.

The baby was then awake and crying for the next 10 minutes, the mom drew a line at 1:25 am and filled in the *Awake and Crying* code. Now, this baby was fed for 20 minutes. A vertical line was drawn at 1:45 am and filled in with the *Feeding* symbol. After the feeding this baby was awake and crying for another 15 minutes, so the mom drew a line at 2:00 am and filled in the *Awake and Crying* symbol.

Let's look over the next example for this particular baby. He woke up again at 3:45, was crying for 10 minutes, then mom fed him for 15 minutes. He was awake and crying for another 65 minutes before going back to sleep. During that time the mom thought he was crying inconsolably for 30 minutes. Of course, every baby is different and your baby's diary may not look like this.

Now why don't you try a couple? *[Give the pen and diary to parent]*
Pretend that you are placing your baby in bed at 12:00 noon and the baby sleeps for 1 hour and 40 minutes.
Now, let's say your baby is awake and crying for the next 20 minutes. *GOOD!*
By the end of the day, the ruler should be completely full with Baby Codes from midnight to midnight.

If there are ever times you can't remember your baby's behaviour. That's Ok! If this is the case, please use the "Cannot Remember" code and draw it in the baby's behaviour ruler.

PARENT CODES:

As you can see on the right side of the sheet, there are two **Parent Codes**. One is for body contact which represents an activity that ***you*** do with your baby. This code goes on the lower half of the ruler and does not have to be all day.
For example, *[show completed Example ruler]* this mother held her baby when he cried from 1:20 am to 1:50 am, so she drew a vertical line at 1:20 am and again at 1:50 am and filled it in with the *Body Contact* code.

The other parent code is the *Moving* code. You can use this code if you have moved your baby by baby carriage or car.
For example, *[show completed Example ruler]* this mother moved her baby either by baby carriage or car from 8:10 am to 8:45 am, so she drew a vertical line at 8:10 am and again at 8:45 am and filled it in with the *Moving* code.

Let's try it. Pretend that you hold your baby for 15 minutes when s/he cries at 1:45 pm to 2:00 pm. *GOOD!*
Pretend that you traveled in a car with your baby for 20 minutes and s/he was awake and content from 2:00 pm to 2:20 pm. *GOOD!*

EVENTS :

In addition to the rulers, there are activities that happen at specific points in time. They may or may not happen; but **if they do it is very important that you record them**. Please mark the events ***above*** the rulers.

For example: Please mark an X each time you place your baby in a car seat while traveling in a car. *[Have parent do it at 12:15 pm]*

If there are times when someone else is taking care of your baby, you may have that person fill in the diary in your absence.

There are just 2 more things we need you to do:

1. Now, there is a simple scale asking "How frustrating to you was your baby's crying today?" Just circle one of the numbers as your answer. For example, if your baby's crying was *somewhat* frustrating on this day, you would circle number three. You only have to do this once a day.

2. Finally, you are asked if this was a typical day. Check yes or no. If no, explain in a word or two why. For example, whether your baby was sick or received an immunization. Things like that.

That's it! Try it! Have fun with the diary but especially with your baby. It will be interesting for you, as well as for all of us, to see how your baby changes, and stays the same, from one day to the next!

- Remember, you are to complete this diary for complete *[number of days as specified by the study]* when your baby is *[age as specified by the study]*. There are blank diary pages attached which you are to complete. We have placed instructions at the back of the booklet should you need to review them.

- Please start the diary on *diary start date.*

- If you have any questions or concerns about the diary, please contact the study team.

THANK YOU!

Appendix Q: Data Graphs of standard scores and quotients on the PDMS-2 results, per infant.

For all figures, annotation "1" refers to baseline assessment, annotation "2" refers to follow-up assessment.

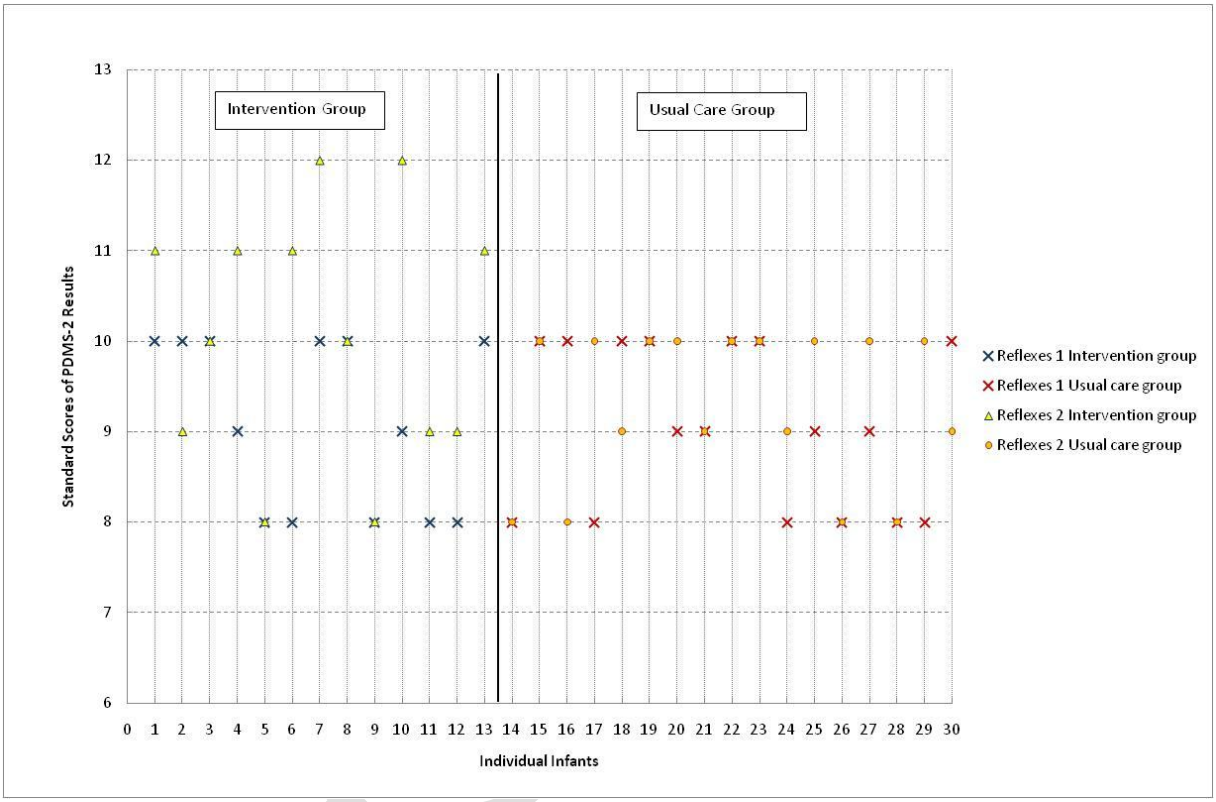


Figure L1: Standard scores for the Reflex subtest, reported for individual infants, clustered by group.

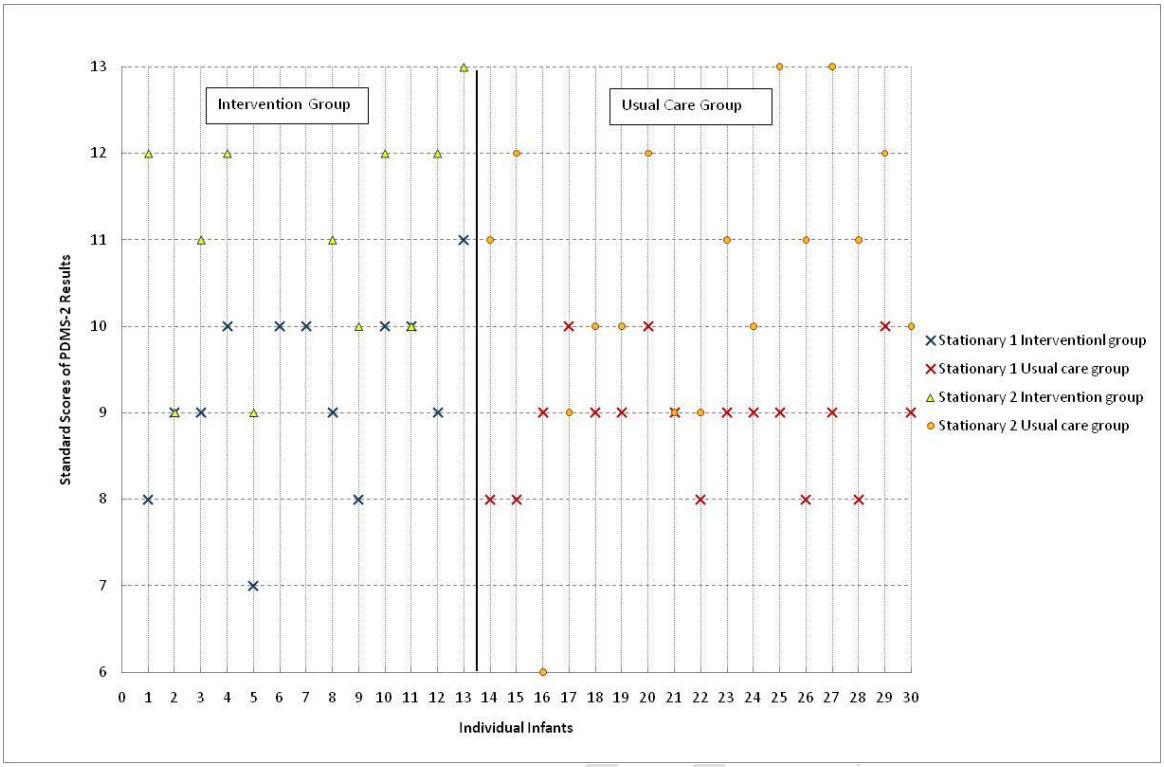


Figure L2: Standard scores for the Stationary subtest, reported for individual infants, clustered by group.

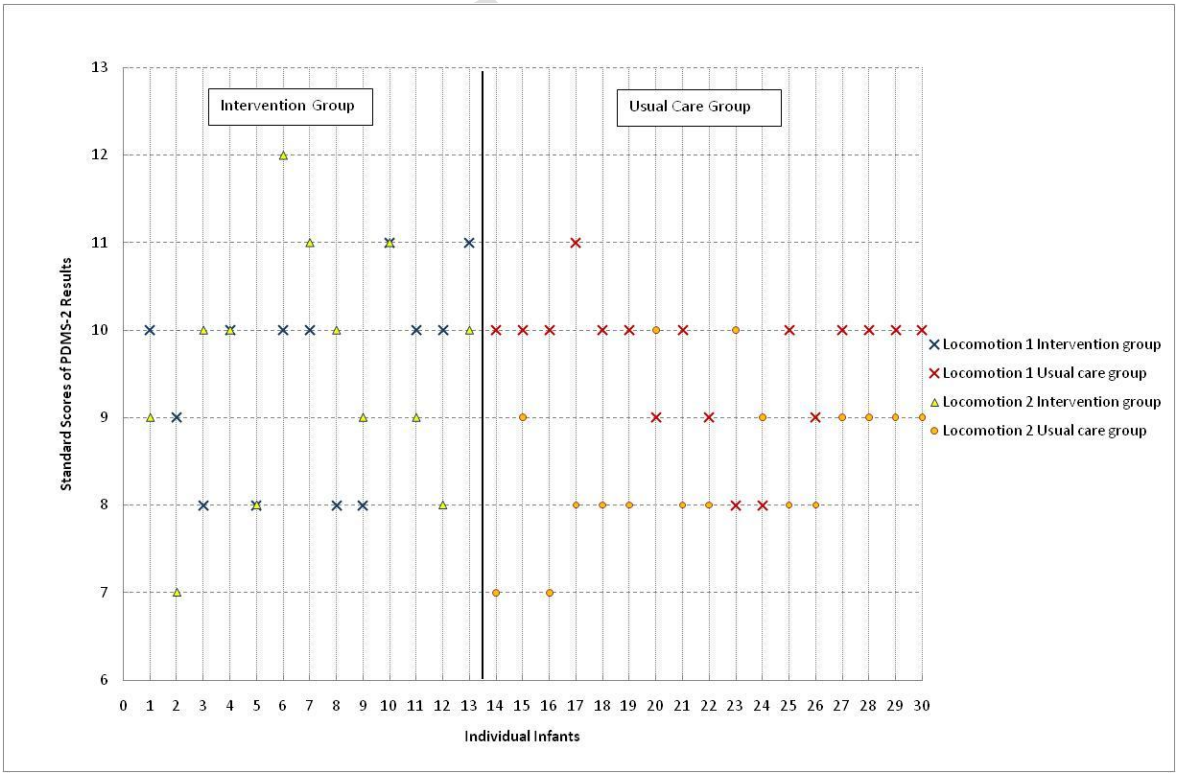


Figure L3: Standard scores for the Locomotion subtest, reported for individual infants, clustered by group.

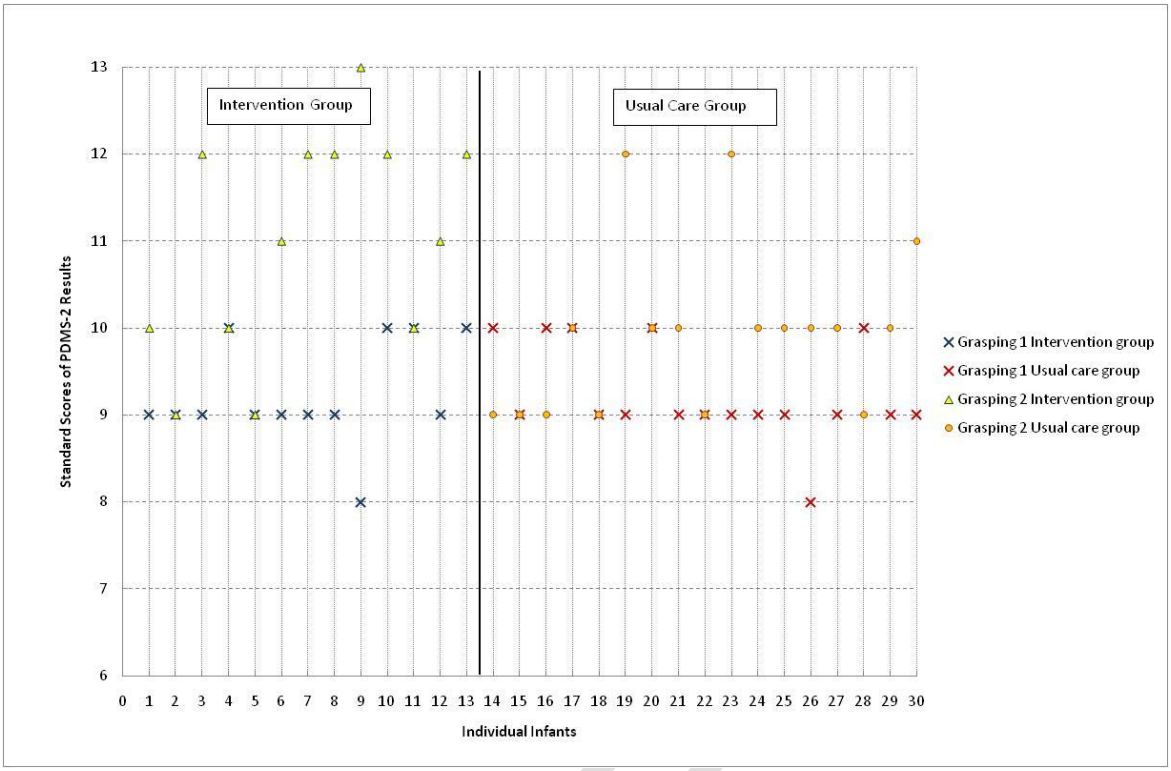


Figure L4: Standard scores for the Grasping subtest, reported for individual infants, clustered by group.

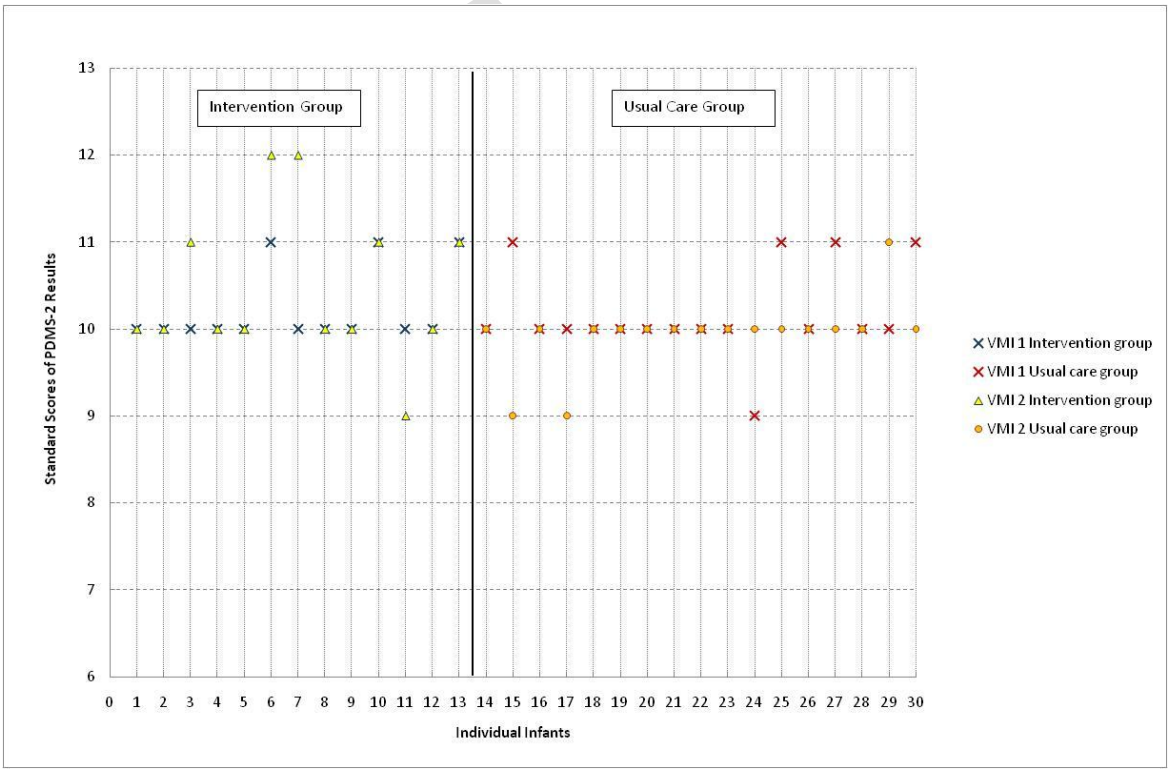


Figure L5: Standard scores for the Visual Motor Integration (VMI) subtest, reported for individual infants, clustered by group.

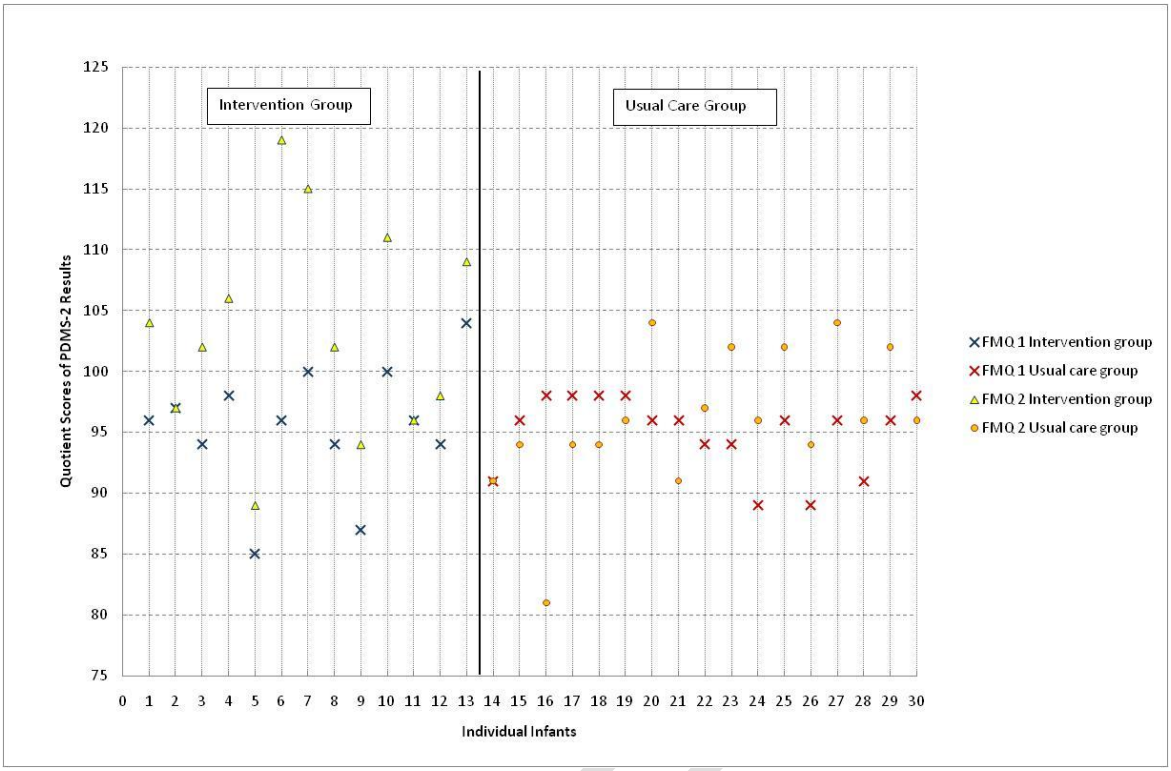


Figure L6: Fine Motor Quotient (FMQ) results, reported for individual infants, clustered by group.

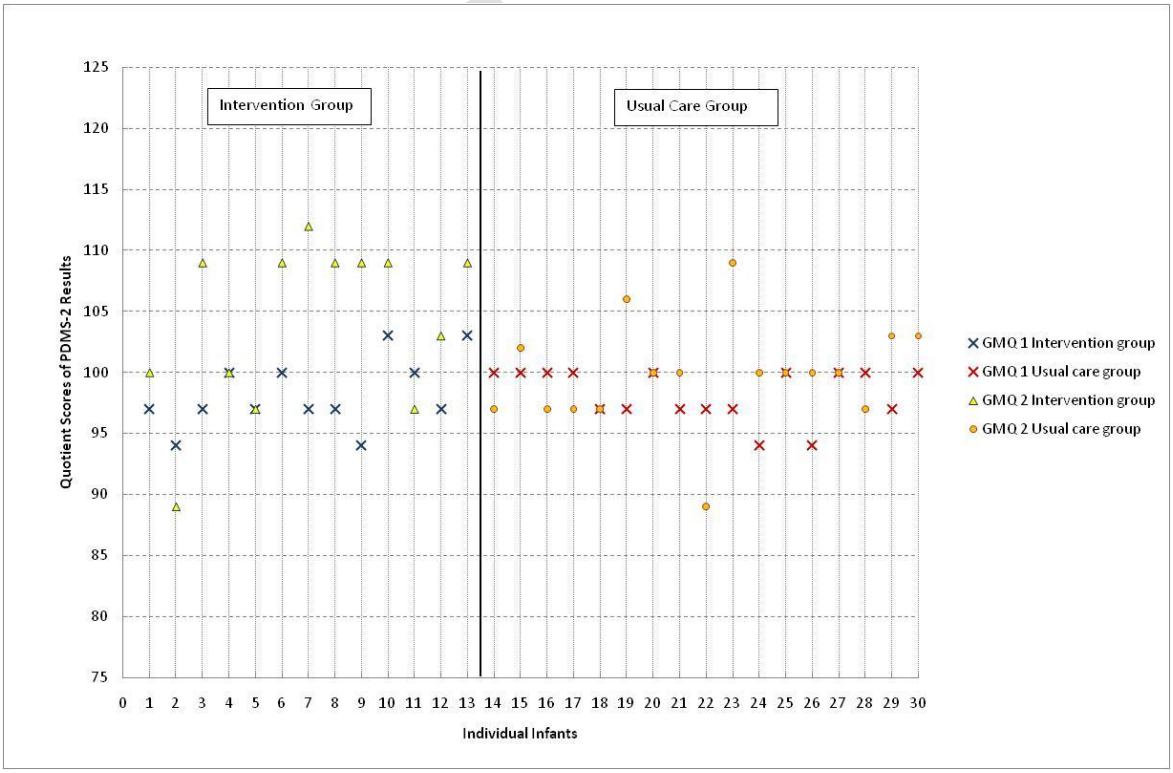


Figure L7: Gross Motor Quotient (GMQ) results, reported for individual infants, clustered by group.

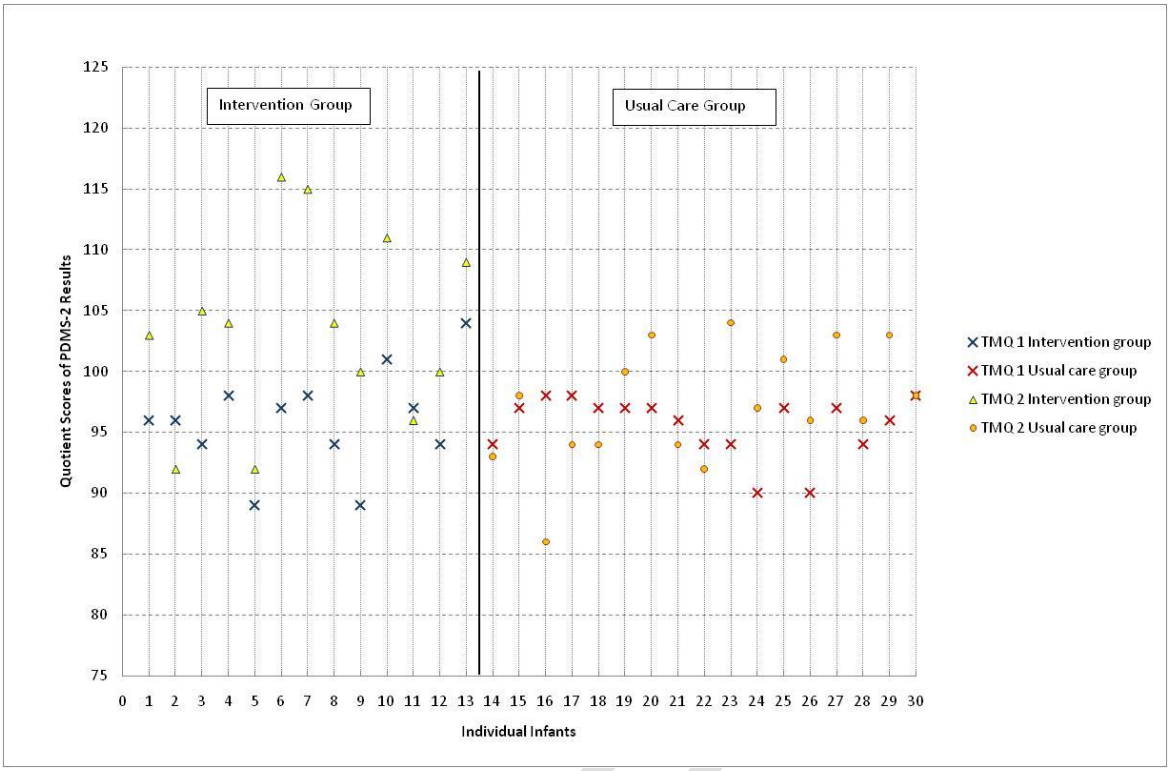


Figure L8: Total Motor Quotient (TMQ) results, reported for individual infants, clustered by group